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 February 29, 2016

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, or a smaller reporting company. See definition of large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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 April 12, 2016: 28,767,582 shares.

PROTALEX, INC.

Quarterly Report on Form 10-Q
For the Period Ended February 29, 2016

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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

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

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

PROTALEX, INC.

CONDENSED STATEMENTS OF OPERATIONS

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

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

PROTALEX, INC.

CONDENSED STATEMENTS OF CASH FLOWS

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

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

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 five clinical studies and PRTX-100 was recently granted Orphan Drug Designation (ODD) in the United States and Europe for the treatment of ITP. The Company does not anticipate generating operating revenue for the foreseeable future and does not currently have any products that are marketable.

NOTE 2. GOING CONCERN

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

There is substantial doubt about the Company's ability to continue as a going concern. From inception through February 29, 2016, the Company has incurred an accumulated deficit of $92,862,330. For the years ended May 31, 2015 and 2014, the Company had net losses of $11,619,796 and $11,852,229, respectively, and for the nine months ended February 29, 2016, the Company had a net loss of $7,655,252. The Company utilized $3,991,479 and $4,623,891 of cash for operating activities for the years ended May 31, 2015 and 2014, respectively, and $3,093,578 during the nine months ended February 29, 2016. As of February 29, 2016, the Company had cash and cash equivalents of $594,701 and net negative working capital of $106,914. The Company has incurred negative cash flow from operating activities since its inception. The Company has spent, and subject to obtaining additional financing, expects to continue to spend, substantial amounts in connection with executing its business strategy, including continued development efforts relating to PRTX-100.

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

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

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, 2015. This Report should be read in conjunction with the Company's Annual Report.

Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions affecting the reported amounts of assets, liabilities, and expense, and the disclosure of contingent assets and liabilities. Estimated amounts could differ from actual results.

Loss per Common Share

The Financial Accounting Standards Board (FASB) has issued guidance for "Earnings Per Share" which provides for the calculation of "Basic" and "Diluted" earnings per share. Basic earnings per share includes no dilution and is computed by dividing net loss to common stockholders by the weighted average number of common shares outstanding for the period. All potentially dilutive securities consisting of employee stock options and warrants have been excluded from the computations since they would be antidilutive. However, these dilutive securities could potentially dilute earnings per share in the future. As of February 29, 2016 and February 28, 2015, the Company had potentially dilutive securities consisting of 4,605,543 and 3,817,543 stock options, respectively.

Cash and Cash Equivalents

For the purposes of reporting cash flows, the Company considers all cash accounts which are not subject to withdrawal restrictions or penalties, and highly liquid investments with original maturities of 90 days or less to be cash and cash equivalents. The cash and cash equivalent deposits are not insured by The Federal Deposit Insurance Corporation.

Reclassifications

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

Research and Development

Research and development costs are expensed as incurred.

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

Share Based Compensation

Effective June 1, 2006, the Company adopted the FASB accounting guidance for fair value recognition provisions of the "Accounting for Share-Based Payment". This standard requires the Company to measure the cost of employee services received in exchange for equity share options granted based on the grant-date fair value of the options. The cost is recognized as compensation expense over the vesting period of the options. The fair value of compensation costs attributed to equity rights issued was $4,044,171 and $6,733,644 and is included in operating expenses for the nine months ended February 29, 2016 and February 28, 2015, respectively. These amounts included both the compensation cost of stock options granted prior to but not yet vested as of June 1, 2006 and compensation cost for all options granted subsequent to May 31, 2006. In accordance with the modified prospective application transition method, prior period results are not restated. Incremental compensation cost for a modification of the terms or conditions of an award is measured by comparing the fair value of the modified award with the fair value of the award immediately before the modification. No tax benefit was recorded as of February 29, 2016 in connection with these compensation costs due to the uncertainty regarding ultimate realization of certain net operating loss carryforwards. The Company has also implemented the SEC interpretations in Staff Accounting Bulletin (SAB) for "Share-Based Payments," in connection with the adoption of FASB accounting guidance.

As of February 29, 2016, the Company had issued 4,607,943 stock options, of which 400 were exercised and 2,000 have expired. Stock options vest pursuant to the terms set forth in individual stock option agreements.

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

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

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

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

At February 29, 2016, there were 4,605,543 stock options outstanding. At February 29, 2016, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model, was approximately $783,836 (net of estimated forfeitures) will be recognized over a weighted average period of eight months through July 2016. The remaining options will be valued once they vest upon the future events. During the nine months ended February 29, 2016, the Company granted an aggregate of 800,000 stock options to four consultants, and one officer/director, all of which have a five year term and an exercise price of $5.41 per share, and 2,000 options expired.

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

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

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

NOTE 4. RECENT ACCOUNTING PRONOUNCEMENTS

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

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

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

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

NOTE 5. RELATED PARTIES

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

During the fiscal year ended May 31, 2015, the Company issued an option for an aggregate of 100,000 shares of its common stock, with par value of $0.00001 per share ("Common Stock") to Marco Elser, a director of the Company. This option has a five year term, an exercise price of $6.00 per share and fully vested on the date of issuance. This option has been valued at $625,000 for which $625,000 of compensation expense has been recorded.

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

During the nine months ended February 29, 2016, the Company issued an option for an aggregate of 250,000 shares of Common Stock to Kirk Warshaw, the CFO and a director of the Company. This option has a five year term, an exercise price of $5.41 per share and vested 50% on the date of issuance and 50% on the one year anniversary. This option has been valued at $1,352,500 of which $1,127,083 of compensation expense has been recorded.

NOTE 6. SENIOR SECURED NOTES - RELATED PARTY

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

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

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

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

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

As of February 29, 2016, the outstanding principal balance under the 2014 Credit Facility totaled $6,065,000. During the nine months ended February 29, 2016, the Company borrowed an aggregate of $2,760,000, $345,000 on each of July 1, 2015, July 31, 2015, August 31, 2015, October 6, 2015, November 10, 2015, December 1, 2015, January 4, 2016, and February 1, 2016. Payment of the principal and accrued interest on the Notes will, at Niobe's election, automatically become immediately due and payable if the Company undertakes certain Fundamental Transactions or upon an Event of Default, both as defined in the Notes. The Company's obligations under the Notes are secured by the Security Agreement, as amended.

NOTE 7. SUBSEQUENT EVENTS

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

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

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

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

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

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

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

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

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

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

In February 2015, we commenced enrollment, at a single U.S. site, of a Phase I/II open-label, multiple, fixed-dose study (the "PRTX-100-105 Study") which is open only to PRTX-100-104 Study patients who indicated their desire for additional treatment. The PRTX-100-105 Study is an open-label, single group study with up to 12 former participants from the 104 Study who will receive a fixed dose of PRTX-100 over a 6-month period. The primary study endpoint of the 105 Study is the safety and tolerability of a fixed dose of PRTX-100 administered over an extended period. The secondary endpoints include 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 nine patients have completed all 105 Study visits.

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

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

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

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

Change in Control and Incremental Financing Transactions

On November 11, 2009 (the "Effective Date"), we consummated a financing transaction (the "Financing") in which we raised $3,000,000 of working capital pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with Niobe Ventures, LLC, a Delaware limited liability company ("Niobe"). Pursuant to the Purchase Agreement, we issued to Niobe (i) 8,695,652 restricted shares of our common stock, with par value of $0.00001 per share ("Common Stock") at a purchase price of $0.23 per share (or $2 million in the aggregate) and (ii) a senior secured convertible promissory note in the principal amount of $1 million convertible into shares of our Common Stock at an initial conversion price equal to $0.23 per share (the "$1 Million Secured Note"). On February 11, 2011, Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of Common Stock.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of February 29, 2016, the outstanding principal balance under the 2014 Credit Facility totaled $6,065,000. During the nine months ended February 29, 2016, we borrowed an aggregate of $2,760,000, $345,000 on each of July 1, 2015, July 31, 2015, August 31, 2015, October 6, 2015, November 10, 2015, December 1, 2015, January 4, 2016, and February 1, 2016. Payment of the principal and accrued interest on the Notes will, at Niobe's election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Notes. Our obligations under the Notes are secured by the Security Agreement, as amended.

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

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

About PRTX-100

PRTX-100, a new generation immunomodulatory therapy, 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. Each of the PRTX-100-103, PRTX-100-104 and the PRTX100-105 studies demonstrated that PRTX-100 was generally safe and well tolerated at all dose levels, and at certain higher doses, more patients showed improvement in measures of disease activity than did patients at the lower dose or placebo cohorts.

Animal Studies

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

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

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

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

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

Clinical Trials

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

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

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

In February 2015, we commenced enrollment, at a single U.S. site, in the PRTX-100-105 Study which is open only to PRTX-100-104 Study patients who indicated their desire for additional treatment. The PRTX-100-105 Study is an open-label, single group study with up to 12 former participants from the 104 Study who will receive a fixed dose of PRTX-100 over a 6-month period. The primary study endpoint of the 105 Study is the safety and tolerability of a fixed dose of PRTX-100 administered over an extended period. The secondary endpoints include 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 nine patients have completed all 105 Study visits.

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

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

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

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

In March 2015, the FDA accepted our Investigational New Drug (IND) application for a Phase I/II open-label, dose-escalating study of PRTX-100 in adults with persistent/chronic ITP (the "PRTX-100-202 Study"). In June 2015, the U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation (ODD) to PRTX-100 for the treatment of ITP. In July 2015, the European Medicines Agency (EMA) granted approval for a Phase 1b open-label, dose-escalating study of PRTX-100 in adult patients with persistent/chronic ITP (the "PRTX-100-203 Study"). In September 2015, the EMA Committee for Orphan Medicinal Products (COMP) issued a positive opinion recommending PRTX-100 for designation as an orphan medicinal product for the treatment of ITP. In November 2015, we enrolled our first patient in the PRTX-100-202 Study and in January 2016 we enrolled our first patient in the PRTX-100-203 Study.

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

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

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

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

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

The PRTX-100-202 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.

The PRTX-100-203 Study

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

The PRTX-100-105 Study

In February 2015 we commenced enrollment, at a single U.S. site, in the PRTX-100-105 Study which is open only to PRTX-100-104 Study patients who indicated their desire for additional treatment. The PRTX-100-105 Study is an open-label, single group study with up to 12 former participants from the 104 Study who will receive a fixed dose of PRTX-100 over a 6-month period. The primary study endpoint of the 105 Study is the safety and tolerability of a fixed dose of PRTX-100 administered over an extended period. The secondary endpoints include 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 nine patients have completed all 105 Study.

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. The stability testing and packaging of the final drug product for clinical supplies is performed by Eurogentec and we believe we have sufficient supply for completion of several future planned clinical studies. 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, we believe the overall costs for these proposed therapeutic doses of PRTX-100 are significantly less due to the low dose and the simplicity of drug substance manufacture.

Markets

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

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

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

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

ITP has no known cure, and relapses may occur years after seemingly successful medical or surgical management. If the patient's condition does not improve with the use of prednisone, a corticosteroid drug that is the first line therapy for ITP, other treatments may include: danazol (Danocrine), a drug taken by mouth; infusions of high-dose gamma globulin (an immune factor); drugs that suppress the immune system; anti-RhD therapy for people with certain blood types; and newer agents like romiplostim (Nplate) and eltrombopag (Promacta) that stimulate the bone marrow to make more platelets. Global sales of Nplate and Promacta were approximately $469 million and $263 million, respectively, in 2014. Neither romiplostim or eltrombopag impact the principal pathological mechanism of ITP, namely immune-mediated plated destruction, and we believe that PRTX-100 may have a more direct impact on ITP disease processes. Thus, we believe that PRTX-100 may complement or reduce the use of thrombopoeitic agents in adult patients with ITP.

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

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

Competition

We believe, based on the pre-clinical trials and the results to date of our five Phase I clinical studies, that PRTX-100 has a potential competitive advantage as it may be safer and more efficacious than existing RA therapies, and may cost less to manufacture than competing biologic-based therapies. Current RA treatments are characterized by complex manufacturing methods and, in 2014, resulted in an average annual retail cost of approximately $13,000 to $30,000 per patient, if the newer disease-modifying anti-rheumatic drugs approved in the last 20 years were used. The cost can increase according to the size/weight of a patient and the number of doses required. Additionally, patients are faced with the cost of the infusion itself and blood tests which are often not included in those cost estimates. A number of pharmaceutical agents are currently being used, with varying degrees of success, to control the signs and symptoms of RA and slow its progression. Available treatment options include:

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

Many large and small pharmaceutical companies are active in this market, with Amgen Corporation (with Pfizer), Johnson & Johnson, Inc. (with Merck) and Abbott Laboratories dominating the market for biologic therapies with their respective products, Enbrel®, Remicade® and Humira®. According to each company's 2014 annual reports, Enbrel generated revenues of approximately $8.5 billion combined for Amgen and Pfizer, Remicade generated revenues of more than $9.2 billion combined for Johnson & Johnson and Merck, and AbbVie reported generated revenues of $12.5 billion for Humira. For other TNF inhibitors, Cimzia generated revenues of $904 million for UCB; Astellas, Simponi generated revenues of $1.9 billion for Johnson & Johnson and Merck, and Orencia generated revenues of $1.7 billion for Bristol Myers Squibb. Kineret, which SOBI acquired the rights to develop and commercialize from Amgen, generated revenues of $75 million in sales in 2014. Actemra and Rituxan generated revenues of $1.34 billion and Rituxan $7.5 billion, respectively, for Roche. Xeljanz earned forgenerated revenues of Pfizer $308 million for Pfizer in 2014. Revenue figures above reflect the use of these drugs for RA, other indications and off label uses.

Post–marketing experience has indicated that current and newly-marketed disease modifying anti-rheumatic drugs (DMARDs) subject patients to an increased risk of certain serious adverse events (SAEs). Products which inhibit the action of TNF-alpha, being the longest on the market and the most studied, have demonstrated an increased incidence of certain SAEs. Due to suppression of the immune system by these products, these SAEs include serious and opportunistic infections such as tuberculosis, fungal infections, and listeria infection, and increased risk of lymphomas. Transient neutropenia and other blood dyscrasias have been reported. TNF inhibitors are also not recommended in patients with demyelinating disease or with congestive heart failure. Rituxan (anti-CD20) use increases the potential for Hep B reactivation and multifocal leukoencephalopathy, a fatal viral disease. Kineret (IL-1) also shows 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 our Annual Report on Form 10-K for the fiscal year ended May 31, 2015.

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

Clinical Trials

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

- *Phase I clinical trials* are initially conducted in a limited population to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients. In some cases, particularly in cancer trials, a sponsor may decide to conduct what is referred to as a “Phase 1b” evaluation, which is a second safety-focused Phase I clinical trial typically designed to evaluate the impact of the drug candidate in combination with currently FDA-approved drugs.

- *Phase II clinical trials* are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine an optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some cases, a sponsor may decide to conduct what is referred to as a "Phase IIb" evaluation, which is a second, confirmatory Phase II clinical trial that could, if positive and accepted by the FDA, serve as a pivotal clinical trial in the approval of a drug candidate.
- *Phase III clinical trials* are commonly referred to as pivotal trials. When Phase II clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

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

Biological License Application

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

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

Fast Track Designation

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

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

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

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

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

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

Regulatory Requirements

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

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

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

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

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

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

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

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. We filed an initial therapeutic use patent application with the U.S. Patent and Trademark Office, or PTO, and in May 2007 the PTO issued us U.S. 7,211,258. The 258 patent has claims relating to the treatment of acute inflammation as well as RA and systemic lupus erythematosis (SLE) using protein A. In September 2008, the PTO issued us U.S. 7,425,331, a second patent claiming the use of protein A to treat ITP or autoimmune thrombocytic purpura. In October 2010, the PTO issued us U.S. 7,807,170, a further patent for the use of protein A. The 170 patent claims the use of protein A to reduce an acute inflammatory response or inflammation, including when these symptoms are associated with myasthenia gravis, ulcerative colitis, Crohn's Disease, psoriatic arthritis or pemphigus vulgaris. In May 2012, the PTO issued us U.S. 8,168,189, a further patent claiming the use of protein A to treat psoriasis and scleroderma. In December 2013, the PTO issued us U.S. 8,603,486, a patent with claims to the use of protein A to treat multiple sclerosis. In addition, we have also filed for foreign patent protection in Canada, Japan and the European Union. Japanese patent JP 4598404 was issued in October 2010, with claims relating to the use of protein A to treat RA, SLE, ITP and autoimmune thrombocytopenia purpura. In April 2014, Japanese patent JP5523796 was issued with claims related to using protein A to treat psoriasis, scleroderma and Crohn's Disease. In September 2015, the European Patent Office issued an Intention to Grant for claims relating to the treatment of numerous autoimmune disorders comprising, but not limited to, RA, ITP, psoriatic arthritis, multiple sclerosis, myasthenia gravis, ulcerative colitis, Crohn's Disease, lupus, pemphigus and

scleroderma.

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

Employees

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

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 February 29, 2016 and February 28, 2015

Research and Development Expenses - Research and Development expenses ("R&D Expenses") were $808,177 and $742,124 for the three months ended February 29, 2016 and February 28, 2015, respectively. The increase in R&D Expenses for the three month period ended February 29, 2016 compared to the three month period ended February 28, 2015 was the result of an increase in the activities associated with the manufacturing of PRTX-100 as well as clinical activities associated with the aforementioned ITP studies.

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 $796,624 and $690,259 for the three months ended February 29, 2016 and February 28, 2015, respectively. The increase in administrative expenses for the three month period ended February 29, 2016 compared to the same prior year period was due to an increase in stock compensation expense.

Professional Fees - Professional expenses were $122,962 and $158,159 for the three months ended February 29, 2016 and February 28, 2015, respectively. The decrease for the three month period ended February 29, 2016 was principally due to a decrease in professional fees.

For the Nine Months Ended February 29, 2016 and February 28, 2015

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

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

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

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

Net Loss Outlook

We have not generated any product sales revenues, have incurred operating losses since inception and have not achieved profitable operations. Our accumulated deficit from inception through February 29, 2016 was $92,862,330 and we expect to continue to incur substantial losses in future periods. We expect that our operating losses in future periods will be the result of continued research and development expenses relating to PRTX-100, as well as costs incurred in preparation for the potential commercialization of PRTX-100.

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

Liquidity and Capital Resources

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

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

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

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

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

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

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

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

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

On July 31, 2015, we filed a Registration Statement on Form S-1 with the SEC (SEC File No. 333-206008) with respect to a proposed public offering of our securities. We are actively seeking 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.

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

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

As of February 29, 2016, the outstanding principal balance under the 2014 Credit Facility totaled $6,065,000. During the nine months ended February 29, 2016, we borrowed an aggregate $2,760,000 pursuant to which we issued eight Notes in the principal amount of $345,000 each (for an aggregate of $2,760,000). Payment of the principal and accrued interest on the Notes will, at Niobe’s election, automatically become immediately due and payable if we undertake certain Fundamental Transactions or upon an Event of Default, both as defined in the Notes. Our obligations under the Notes are secured by the Security Agreement, as amended.

Subsequent Events

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

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

Our operating cash outflows for the nine months ended February 29, 2016 and February 28, 2015 have resulted primarily from research and development expenditures associated for PRTX-100 and administrative purposes. We expect to continue to use cash resources to fund operating losses and expect to continue to incur operating losses in this fiscal year and beyond due to continuing research and development activities.

Net Cash Used in Investing Activities and Investing Requirements Outlook

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

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

Off-Balance Sheet Arrangements

As of February 29, 2016, we had no off-balance sheet arrangements such as guarantees, retained or contingent interest in assets transferred, obligation under a derivative instrument and obligation arising out of or a variable interest in an unconsolidated entity.

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	Final Form of Secured Promissory Note issued to Niobe pursuant to the Amended and Restated 2014 Credit Facility Agreement between the Company and Niobe dated as of December 1, 2015.	Previously filed on January 7, 2016 as Exhibit 4.2 to the Quarterly Report on Form 10Q for the period ended November 30, 2015 and incorporated herein by reference.
10.1	Final Form of the Amended and Restated 2014 Credit Facility Agreement between the Company and Niobe dated as of December 1, 2015.	Previously filed on December 7, 2015, as Exhibit 10.1 to the Company's Current Report on Form 8K and incorporated herein by reference.
10.2	Final Form of the Third Consolidated, Amended and Restated Security Agreement between the Company and Niobe dated as of December 1, 2015.	Previously filed on December 7, 2015, as Exhibit 10.1 to the Company's Current Report on Form 8K and incorporated herein by reference.
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: April 12, 2016

PROTALEX, INC.

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

Date: April 12, 2016

By: /s/ Kirk M. Warshaw
Kirk M. Warshaw, Chief Financial Officer
(Principal 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: April 12, 2016

/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: April 12, 2016

/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 February 29, 2016 as filed with the Securities and Exchange Commission (the "Report"), I, Arnold P. Kling, President of the Company, certify, pursuant to 18 U.S.C. ss. 1350, as adopted pursuant to ss. 906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: April 12, 2016

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

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

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 February 29, 2016 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: April 12, 2016

/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.