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

FORM 10-Q

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

For the quarterly period ended August 31, 2011

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)**

133 Summit Avenue, Suite 22
Summit, NJ 07901
(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 **September 28, 2011**: 18,926,615 shares.

PROTALEX, INC.

Quarterly Report on Form 10-Q
For the Period Ended August 31, 2011

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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.
(A Development Stage Company)
BALANCE SHEETS

	August 31, 2011 (Unaudited)	May 31, 2011
CURRENT ASSETS:		
Cash and cash equivalents	$ 972,113	$ 1,542,025
Prepaid expenses	16,347	38,441
Total current assets	988,460	1,580,466
OTHER ASSETS:		
Intellectual technology property, net of accumulated amortization of $11,283 and $11,028 as of August 31, 2011 and May 31, 2011, respectively	8,252	8,507
Total other assets	8,252	8,507
Total Assets	$ 996,712	$ 1,588,973
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES:		
Accounts payable	$ 182,861	$ 182,861
Accrued expenses	183,201	253,311
Total current liabilities	366,062	436,172
LONG TERM LIABILITIES:		
Senior Secured Convertible Note – net of debt discount - related party	895,033	660,975
Total liabilities	1,261,095	1,097,147
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, par value $0.00001, 1,000,000 shares authorized; none issued and outstanding	-	-
Common stock, par value $0.00001, 100,000,000 shares authorized; 18,926,615 shares issued and outstanding, respectively	189	189
Additional paid in capital	51,577,731	51,501,872
Deficit accumulated during the development stage	(51,842,303)	(51,010,235)
Total stockholders' equity (deficit)	(264,383)	491,826
Total liabilities and stockholders' equity (deficit)	$ 996,712	$ 1,588,973

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENTS OF OPERATIONS

	Three Months Ended August 31, 2011	Three Months Ended August 31, 2010	From Inception (September 17, 1999) Through August 31, 2011
	(Unaudited)	(Unaudited)	(Unaudited)
Revenues	$ -	$ -	$ -
Operating Expenses			
Research and development (including depreciation and amortization)	354,092	330,770	30,996,184
Administrative (including depreciation and amortization)	178,589	113,164	17,356,005
Professional fees	65,836	68,631	4,386,991
Depreciation and amortization	255	255	181,181
Operating loss	(598,772)	(512,820)	(52,920,361)
Other income (expense)			
Interest income	762	2,154	2,207,045
Interest expense	(234,058)	(51,311)	(1,128,987)
Net loss	$ (832,068)	$ (561,977)	$ (51,842,303)
Weighted average number of common shares outstanding	**18,926,615**	**14,415,745**	
Loss per common share – basic and diluted	$ (0.04)	$ (0.04)	

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

From Inception (September 17, 1999) through August 31, 2011

(Unaudited)

	Common Stock		Additional Paid in	Common Stock-	Deficit Accumulated During The Development	
	Shares	Amount	Capital	Contra	Stage	Total
September 17, 1999 — initial issuance of 2,000 shares for intellectual technology license at $.15 per share	2,000	$ 300	$ —	$ —	$ —	$ 300
September 30, 1999 — cost of public shell acquisition over net assets acquired to be accounted for as a Recapitalization	—	—	—	(250,000)	—	(250,000)
October 27, 1999 — issuance of 17 shares to individual for $25,000	17	25,000	—	—	—	25,000
November 15, 1999 — reverse merger transaction with Enerdyne Corporation, net transaction amounts	1,794,493	118,547	—	(118,547)	—	—
November 18, 1999 — February 7, 2000 — issuance of 91,889 shares to various investors at $1.80 per share	91,889	165,400	—	—	—	165,400
January 1, 2000 — issuance of 20,000 shares in exchange for legal services	20,000	15,000	—	—	—	15,000
May 1 - 27, 2000 — issuance of 128,000 shares to various investors at $5.00 per share	128,000	640,000	—	—	—	640,000
May 27, 2000 — issuance of 329 shares to an individual in exchange for interest Due	329	1,644	—	—	—	1,644
Net loss for the year ended May 31, 2000	—	—	—	—	(250,689)	(250,689)
Balance, May 31, 2000	2,036,728	965,891	—	(368,547)	(250,689)	346,655
December 7, 2000 — issuance of 85,000 shares to various investors at $5.00 per share	85,000	425,000	—	—	—	425,000
May 31, 2001 — Forgiveness of debt owed to stockholder	—	—	40,000	—	—	40,000
Net loss for the year ended May 31, 2001	—	—	—	—	(553,866)	(553,866)
Balance, May 31, 2001	2,121,728	1,390,891	40,000	(368,547)	(804,555)	257,789

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) - (continued)

From Inception (September 17, 1999) through August 31, 2011

(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock-Contra	Deficit Accumulated During The Development Stage	Total
August 13, 2001 — Contribution by Stockholders	—	—	143,569	—	—	143,569
November 7, 2001 — issuance of 176,320 Shares at $6.25 per share	176,320	1,102,000	—	—	—	1,102,000
November 26, 2001 — options issued to board member	—	—	133,000	—	—	133,000
Net loss for the year ended May 31, 2002	—	—	—	—	(1,280,465)	(1,280,465)
Balance, May 31, 2002	2,298,048	2,492,891	316,569	(368,547)	(2,085,020)	355,893
July 5, 2002 — issuance of 168,400 shares at $7.50 per share	168,400	1,263,000	—	—	—	1,263,000
July 1, 2002 - May 1, 2003 – purchase of common stock from stockholder at $3.50 per share	(26,191)	(91,667)	—	—	—	(91,667)
January 15, 2003 - May 15, 2003 — common stock issued to Company president	8,334	82,841	—	—	—	82,841
May 14, 2003 — common stock issued to employee	1,000	11,250	—	—	—	11,250
June 1, 2002 - May 31, 2003 – compensation related to stock options issued to board members, employees and consultants	—	—	287,343	—	—	287,343
Net loss for the year ended May 31, 2003	—	—	—	—	(1,665,090)	(1,665,090)
Balance, May 31, 2003	2,449,591	3,758,315	603,912	(368,547)	(3,750,110)	243,570
June 15, 2003, common stock issued to Company president	1,667	16,418	—	—	—	16,418
June 15, 2003, purchase of common stock from stockholder	(2,419)	(8,333)	—	—	—	(8,333)
September 18, 2003 – issuance of 1,489,129 of common stock issued in private placement At $8.50 per share, net of transaction costs	1,489,129	11,356,063	—	—	—	11,356,063
September 19, 2003 – repurchase and retired 598,961 shares for $300,000	(598,961)	(300,000)	—	—	—	(300,000)
December 12, 2003 – issuance of 7,880 shares to terminated employees at $13.00 per share	7,880	102,438	—	—	—	102,438
March 1, 2004 – common stock issued to employee at $12.75 per share	10,000	127,500	—	—	—	127,500
May 31, 2004 – reclassify common stock contra to common stock	—	(368,547)	—	368,547	—	—

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) - (continued)

From Inception (September 17, 1999) through August 31, 2011

(Unaudited)

	Common Stock		Additional Paid in	Common Stock-	Deficit Accumulated During The Development	
	Shares	Amount	Capital	Contra	Stage	Total
June 1, 2003 – May 31, 2004 – compensation related to stock options issued to board members, employees and consultants	—	—	448,096	—	—	448,096
Net loss for the year ended May 31, 2004	—	—	—	—	(2,989,364)	(2,989,364)
Balance, May 31, 2004	3,356,887	14,683,854	1,052,008	—	(6,739,474)	8,996,388
November 30, 2004 – adjust March 1, 2004 common stock issued to employee	—	(20,000)		—	—	(20,000)
January 13, 2005 – common stock issued to employee at $12.75 per share	3,000	38,250	—	—	—	38,250
February 28, 2005 – Reclass Par Value for Reincorporation into DE as of 12/1/04	—	(14,702,070)	14,702,070	—	—	—
May 25, 2005 - issuance of 518,757 shares of common stock issued in private placement At $9.75 per share, net of transaction costs	518,757	5	4,851,188	—	—	4,851,193
June 1, 2004 – May 31, 2005 – compensation related to stock options issued to board members, employees and consultants	—	—	308,711	—	—	308,711
Net loss for the year ended May 31, 2005	—	—	—	—	(5,567,729)	(5,567,729)
Balance, May 31, 2005	3,878,644	39	20,913,977	—	(12,307,203)	8,606,813
August 23, 2005 – common stock issued to employee	8,000	—	100,000	—	—	100,000
October 19, 2005 – common stock issued to employee	2,000	—	25,000	—	—	25,000
December 30, 2005 – issuance of 519,026 shares of common stock issued in private placement at $11.25 per share, net of transaction costs	519,026	5	5,510,962	—	—	5,510,967
June 1, 2005 – May 31, 2006 – warrants exercised	70,320	1	786,537	—	—	786,538
June 1, 2005– May 31, 2006 – compensation related to stock options issued to board members, employees and consultants	—	—	404,679	—	—	404,679
Net loss for the year ended May 31, 2006	—	—	—	—	(6,104,402)	(6,104,402)
Balance, May 31, 2006	4,477,990	45	27,741,155	—	(18,411,605)	9,329,595

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

PROTALEX, INC.

(A Development Stage Company)

STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT) - (continued)

From Inception (September 17, 1999) through August 31, 2011

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock-Contra	Deficit Accumulated During The Development Stage	Total
July 7, 2006 – issuance of 1,214,203 shares of common stock issued in private placement at $12.50 per share, net of transaction costs	1,214,203	12	14,217,709	—	—	14,217,721
June 1, 2006 – May 31, 2007 – warrants exercised	26,700	-	300,374	—	—	300,374
June 1, 2006 – May 31, 2007 – stock options exercised	1,200	-	15,200	—	—	15,200
June 1, 2006 – May 31, 2007 – share based compensation to board members, employees and consultants	—	—	1,826,850	—	—	1,826,850
Net loss for the year ended May 31, 2007	—	—	—	—	(8,451,942)	(8,451,942)
Balance, May 31, 2007 – (Unaudited)	5,720,093	57	44,101,288	—	(26,863,547)	17,237,798
June 1, 2007 – May 31, 2008 – share based compensation to board members, employees and consultants	—	—	1,011,025	—	—	1,011,025
Net loss for the year ended May 31, 2008	—	—	—	—	(10,490,758)	(10,490,758)
Balance, May 31, 2008 – (Unaudited)	5,720,093	57	45,112,313	—	(37,354,305)	7,758,065
June 1, 2008 – May 31, 2009 – shared-based compensation to board members, employees and consultants	—	—	753,268	—	—	753,268
Net loss for the year ended May 31, 2009	—	—	—	—	(7,230,206)	(7,230,206)
Balance, May 31, 2009	5,720,093	57	45,865,581	—	(44,584,511)	1,281,127
June 1, 2009 – May 31, 2010 – shared-based expense to employees and debt holders	—	—	335,741	—	—	335,741
November 11, 2009 – record beneficial conversion value attached to senior secured convertible debt	—	—	521,793	—	—	521,793
November 11, 2009 – issuance of 8,695,692 shares of common stock at $.23	8,695,652	87	1,999,913	—	—	2,000,000
Net loss for the year ended May 31, 2010	—	—	—	—	(3,067,842)	(3,067,842)
Balance, May 31, 2010	14,415,745	144	48,723,028	—	(47,652,353)	1,070,819
June 1, 2010 – May 31, 2011 – shared-based expense to employees and debt holders	—	—	124,722	—	—	124,722
February 11, 2011 – record beneficial conversion value attached to senior secured convertible debt	—	—	1,616,667	—	—	1,616,667
February 11, 2011 – issuance of 4,510,870 shares of common stock	4,510,870	45	1,037,455	—	—	1,037,500
Net loss for the year ended May31, 2011	—	—	—	—	(3,357,882)	(3,357,882)
Balance, May 31, 2011	18,926,615	189	51,501,872	—	(51,010,235)	491,826
June 1, 2011 – August 31, 2011 – shared-based expense to employees	—	—	75,859	—	—	75,859
Net loss for the three months ended August 31, 2011	—	—	—	—	(832,068)	(832,068)
Balance, August 31, 2011 (Unaudited)	18,926,615	$ 189	$ 51,577,731	$ —	$ (51,842,303)	$ (264,383)

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

PROTALEX, INC.
(A Development Stage Company)
STATEMENTS OF CASH FLOWS

	Three Months Ended August 31, 2011	Three Months Ended August 31, 2010	From Inception (September 17, 1999) Through August 31, 2011
	(Unaudited)	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (832,068)	$ (561,977)	$ (51,842,303)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities			
(Gain) on disposal of equipment, net	—	—	(81,544)
Depreciation and amortization	255	255	1,035,834
Equity based expense	309,917	51,311	7,167,769
(Increase)/decrease in:			
Prepaid expenses and deposits	22,094	22,490	(24,337)
Increase/(decrease) in:			
Accounts payable and accrued expenses	(70,110)	64,849	366,060
Payroll and related liabilities	—	(100,001)	—
Net cash and cash equivalents used in operating activities	(569,912)	(523,073)	(43,378,521)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Acquisition of intellectual technology license – fee portion	—	—	(20,000)
Refund of security deposits	—	—	7,990
Acquisition of equipment	—	—	(905,936)
Excess of amounts paid for public shell over assets acquired to be accounted for as a recapitalization	—	—	(250,000)
Proceeds from disposal of equipment	—	—	229,135
Net cash and cash equivalents used in investing activities	—	—	(938,811)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from stock issuance, including options and warrants exercised	—	—	42,658,458
Principal payment on equipment notes payable and capital leases	—	—	(295,411)
Contribution by stockholders	—	—	183,569
Principal payment on note payable to individuals	—	—	(225,717)
Issuance of note payable to individuals	—	—	3,368,546
Acquisition of common stock	—	—	(400,000)
Net cash and cash equivalents provided by financing activities	—	—	45,289,445
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(569,912)	(523,073)	972,113
Cash and cash equivalents, beginning of period	1,542,025	2,350,084	—
Cash and cash equivalents, ending of period	$ 972,113	$ 1,827,011	$ 972,113
SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:			
Interest paid	$ —	$ —	$ 66,770
Taxes paid	$ —	$ —	$ 100
NON-CASH FINANCING ACTIVITIES:			
Conversion of debt for equity	$ —	$ —	$ 1,037,500

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

PROTALEX, INC.

(A Company in the Development Stage)

NOTES TO UNAUDITED FINANCIAL STATEMENTS

From Inception (September 17, 1999) through August 31, 2011

NOTE 1. ORGANIZATION AND BUSINESS ACTIVITIES

Protalex, Inc., a Delaware corporation, ("we," "us," "our," the "Company" or "its") is a development stage company which has been engaged in developing a class of biopharmaceutical drugs for treating autoimmune inflammatory diseases. Our lead product, PRTX-100, is formulated with highly-purified staphylococcal protein A, which is an immune modulating protein produced by bacteria. The Company does not anticipate generating operating revenue for the foreseeable future.

PRTX-100 has demonstrated effectiveness in animal models of autoimmune diseases as well as demonstrated activity on cultured human immune cells at very low concentrations, although the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we would see in future human clinical trials. The safety, tolerability, and pharmacokinetics ("PK") of PRTX-100 in humans have now been characterized in three clinical studies. In August 2010, the Company commenced a multi-center Phase 1b clinical trial of PRTX-100 in South Africa on adult patients with active rheumatoid arthritis (RA) and dosed its first patient enrolled in the study (the "RA Study"). The RA Study which is a proof of concept study to evaluate safety and potential efficacy of PRTX-100 in patients with active RA, will enroll up to 40 patients in four cohorts and is expected to be completed in the fourth calendar quarter of 2011. In June 2011 our first patients were enrolled in the fourth cohort of the RA Study and the dose administered was increased by a factor of 0.67 times from the third cohort. We currently have no products on the market.

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 following the change in control transaction more fully described below. The Company is currently actively pursuing the commercial development of PRTX-100 for the treatment of RA.

The Company maintains an administrative office in Summit, 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.

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

NOTE 2. CHANGE OF OWNERSHIP TRANSACTION

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

For the purpose of providing the Company with additional working capital, on February 11, 2011, pursuant to a Credit Facility Agreement dated as of December 2, 2009 (the "Facility") between the Company and Niobe, the Company issued to Niobe a senior secured convertible promissory note in the principal amount of $2 million (the "$2 Million Secured Note"). The $2 Million Secured Note is convertible into shares of Common Stock at a conversion price equal to $0.23 per share, for an aggregate of 8,695,652 shares of Common Stock (net of accrued interest thereon), bears interest at a rate of 3% per annum and matures on December 31, 2012.

NOTE 2. CHANGE OF OWNERSHIP TRANSACTION (continued):

Our obligations under the $2 Million Secured Note are secured by an Amended Security Agreement (as defined in Note 8, below) which granted Niobe a security interest in substantially all of our personal property and assets, including our intellectual property. The $2 Million Secured Note is 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 Note will automatically be converted if we undertake certain Fundamental Transactions, as defined in the $2 Million Secured 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 Note also provides 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 Note.

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 president and elected Kirk M. Warshaw as chief financial officer and secretary of the Company.

In addition, on the Effective Date, we terminated (i) the Investor Rights Agreement dated September 18, 2003 among us, vSpring SBIC L.P. ("vSpring") and certain of the investors set forth on Schedule A thereto (the "2003 IRA") and the Registration Rights Agreement dated May 25, 2005 among us, vSpring and certain of the investors set forth on Schedule I thereto (the "2005 RRA") in accordance with their respective terms and (ii) stock options exercisable for an aggregate of 246,714 shares of our Common Stock (approximately 41% of our then outstanding stock options), all of which were held by three option holders, Steven H. Kane, our former CEO ("Kane"), Marc L. Rose, our former CFO ("Rose") and vSpring.

The securities issued in the Financing 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(6) 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.

NOTE 3. 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 are regulatory approved and market accepted. There is no assurance that these plans will be realized in whole or in part. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Since inception, the Company has incurred an accumulated deficit of $51,842,303 through August 31, 2011. For the years ended May 31, 2011 and 2010, the Company had net losses of $3,357,882 and $3,067,842, respectively and for the three months ended August 31, 2011, the Company had a net loss of $832,068 . The Company has used $2,808,059 and $3,318,333 of cash in operating activities for the years ended May 31 2010 and 2010, respectively and $569,912 during the three months ended August 31, 2011. As of August 31, 2011, the Company had cash and cash equivalents of $972,113 and net working capital of $622,398. 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 clinical trials in fiscal year 2012 and that it will need to raise additional capital in the future to fund the ongoing FDA approval process. If the Company is unable to obtain approval of its future IND applications or otherwise advance in the FDA approval process, its ability to sustain its operations would be significantly jeopardized.

NOTE 3. GOING CONCERN (Continued):

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

NOTE 4. BASIS OF PRESENTATION

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 Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America 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, 2011. This quarterly report should be read in conjunction with our annual report.

NOTE 5. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents

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

Estimates

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

Loss per Common Share

The Financial Accounting Standards Board (FASB) has issued guidance for "Earnings Per Share" which provides for the calculation of "Basic" and "Diluted" earnings per share. Basic earnings per share includes no dilution and is computed by dividing net loss to common stockholders by the weighted average number of common shares outstanding for the period. All potentially dilutive securities consisting of employee stock options and warrants have been excluded from the computations since they would be antidilutive. However, these dilutive securities could potentially dilute earnings per share in the future. As of August 31, 2011 the Company had potentially dilutive securities consisting of 1,538,927 stock options. As of August 31, 2010, the Company had potentially dilutive securities consisting of warrants and stock options totaling 2,264,706 comprised of 785,779 warrants and 1,478,927 stock options.

NOTE 5. 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" using the modified prospective method. This standard requires the Company to measure the cost of employee services received in exchange for equity share options granted based on the grant-date fair value of the options. The cost is recognized as compensation expense over the vesting period of the options. Under the modified prospective method, $75,859 and $0 compensation cost is included in operating expenses for the three months ended August 31, 2011 and 2010 , respectively. These amounts included both the compensation cost of stock options granted prior to but not yet vested as of June 1, 2006 and compensation cost for all options granted subsequent to May 31, 2006. In accordance with the modified prospective application transition method, prior period results are not restated. Incremental compensation cost for a modification of the terms or conditions of an award is measured by comparing the fair value of the modified award with the fair value of the award immediately before the modification. No tax benefit was recorded as of May 31, 2010 in connection with these compensation costs due to the uncertainty regarding ultimate realization of certain net operating loss carryforwards. The Company has also implemented the SEC interpretations in Staff Accounting Bulletin ("SAB") for "Share-Based Payments", in connection with the adoption of FASB accounting guidance.

The Board of Directors adopted and the stockholders approved the 2003 Stock Option Plan on October 2003 and it was amended in October 2005. The plan was adopted to recognize the contributions made by the Company's employees, officers, consultants, and directors, to provide those individuals with additional incentive to devote themselves to the Company's future success, and to improve the Company's ability to attract, retain and motivate individuals upon whom the Company's growth and financial success depends. Under the plan, stock options may be granted as approved by the Board of Directors or the Compensation Committee. There are 900,000 shares reserved for grants of options under the plan, of which 88,800 have been issued and 800 were exercised. The Company has issued 271,784 stock options as standalone grants, of which 400 were exercised. Stock options vest pursuant to individual stock option agreements. No options granted under the plan are exercisable after the expiration of ten years (or less in the discretion of the Board of Directors or the Compensation Committee) from the date of the grant. The plan will continue in effect until terminated or amended by the Board of Directors.

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

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

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

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

As of August 31, 2011, there were 1,538,927 stock options outstanding. At August 31, 2011, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model was approximately $404,584 (net of estimated forfeitures) will be recognized ratably through December 31, 2012. The remaining amount of options will be valued once they vest upon the future events. During the three months ended August 31, 2011, the Company has not granted any stock options and no options were forfeited or expired.

NOTE 5. 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:

	Three Months Ended August 31, 2011	Three Months Ended August 31, 2010	From Inception Through August 31, 2011
Dividends per year	0	0	0
Volatility percentage	97.5%	97.5%	90%-112%
Risk free interest rate	3.47%	3.47%	2.07%-5.11%
Expected life (years)	5.0-9.0	5.0-9.0	3-9
Weighted Average Fair Value	$ 1.10	$ .45	$ 5.20

NOTE 6. 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.

NOTE 7. RELATED PARTIES

Niobe, our majority stockholder and the holder of our $2 Million Secured Note, is controlled by Arnold P. Kling, our president and director.

During the year ended May 31, 2010, the Company issued an aggregate of 950,543 options to John Doherty, one of our directors, and Kirk M. Warshaw, our chief financial officer and director. No options were issued to any related party during the three months ended August 31, 2011.

The Company's principal offices are located at 133 Summit Avenue, Suite 22, Summit, New Jersey which are owned by Kirk M. Warshaw, LLC (the "LLC"), an affiliated company of Kirk Warshaw, the Company's chief financial officer. The Company occupies its principal offices on a month to month basis. On March 1, 2010, it began paying a monthly fee of $500 to the LLC for the use and occupancy, and administrative services, related to its principal offices.

NOTE 8. SENIOR SECURED CONVERTIBLE NOTES - RELATED PARTY

On the Effective Date, the Company issued the $1 Million Secured Note to Niobe, its majority stockholder which is controlled by Arnold P. Kling, our president and director. The $1 Million Secured Note bore interest at a rate of 3% per annum and had a scheduled maturity on November 13, 2012. Our obligations under the $1 Million Secured Note were secured by a Security Agreement dated the Effective Date (the "Security Agreement") which granted Niobe a security interest in substantially all of our personal property and assets, including our intellectual property. On February 11, 2011, Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of our Common Stock.

The Company evaluated the conversion feature of the $1 Million Secured Note and determined that under the accounting guidance for "Accounting for Convertible Securities with Beneficial Conversion Features" that a value should be attributed to the embedded conversion feature. On the date of issuance of the Secured Note, the fair market value of the Company's Common Stock was $0.35 per share. The Company determined the allocation to the conversion feature to be $521,793 which reduced the face amount of the convertible debt carried on our balance sheet.

NOTE 8. SENIOR SECURED CONVERTIBLE NOTES - RELATED PARTY (continued):

On December 2, 2009, the Company entered into the Facility with Niobe pursuant to which Niobe agreed to provide up to $2.0 million of additional capital in the form of secured loans at any time prior to June 30, 2012 subject to the achievement of certain predetermined benchmarks. In connection with the Facility, on December 2, 2009, the Security Agreement securing our obligations under the $1 Million Secured Note was amended and restated to also secure any incremental obligations under the Facility (the "Amended Security Agreement"). Pursuant to the Amended Security Agreement, Niobe has a security interest in substantially all of our personal property and assets, including its intellectual property to collateralize all amounts due to it under the $1 Million Secured Note and the Facility.

Pursuant to the Facility, on February 11, 2011, we received $2 million of additional working capital from Niobe and issued the $2 Million Secured Note to Niobe. The $2 Million Secured Note bears interest at a rate of 3% per annum and matures on December 31, 2012.

Our obligations under the $2 Million Secured Note are secured by an Amended Security Agreement. The $2 Million Secured Note is 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 Note will automatically be converted if we undertake certain Fundamental Transactions, as defined in the $2 Million Secured 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 Note also provides 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 Note.

The Company evaluated the conversion feature of the $2 Million Secured Note and determined that under the accounting guidance for "Accounting for Convertible Securities with Beneficial Conversion Features" that a value should be attributed to the embedded conversion feature. On February 11, 2011, the date of issuance of the $2 million Secured Note, the fair market value of the Company's Common Stock was $1.20 per share. The Company determined the allocation to the conversion feature to be $1,616,667 which reduced the face amount of the convertible debt carried on our balance sheet. This discount will be amortized over 22 months and will serve to increase the interest expense of the $2 Million Secured Note during its term.

NOTE 9. SUBSEQUENT EVENTS

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

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

Overview

We are a development stage company which has been engaged in developing a class of biopharmaceutical drugs for treating autoimmune inflammatory diseases. Our lead product PRTX-100, is formulated with highly-purified staphylococcal protein A, which is an immune modulating protein produced by bacteria.

PRTX-100 has demonstrated effectiveness in animal models of autoimmune diseases as well as demonstrated activity on cultured human immune cells at very low concentrations, although the effectiveness of PRTX-100 shown in pre-clinical studies using animal models may not be predictive of the results that we would see in future human clinical trials. The safety, tolerability, and pharmacokinetics ("PK") of PRTX-100 in humans have now been characterized in three clinical studies in the United States. A proof of concept study to evaluate safety and potential efficacy of PRTX-100 in patients with active rheumatoid arthritis ("RA") is now underway in South Africa and is expected to be completed in the fourth calendar quarter of 2011 (the "RA Study"). In June 2011 our first patients were enrolled in the fourth cohort of the RA Study and the dose administered was increased by a factor of 0.67 times from the third cohort. We currently have no products on the market.

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 new management took control of our operations in November 2009 following the "change in control" transaction described below. We are currently actively pursuing the commercial development of PRTX-100 for the treatment of RA.

We maintain an administrative office in Summit, 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 and facilities.

Change in Control Transaction

On November 11, 2009 (the "Effective Date"), we consummated a financing transaction, that resulted in a change in control in which we raised $3,000,000 of additional working capital pursuant to a Securities Purchase Agreement (the "Purchase Agreement") with Niobe Ventures, LLC ("Niobe"), a Delaware limited liability company (the "Financing"). Pursuant to the Purchase Agreement, we issued to Niobe (i) 8,695,652 restricted shares of our common stock at a purchase price of $0.23 per share (or $2,000,000 in the aggregate) and (ii) a senior secured convertible promissory note in the principal amount of $1,000,000 convertible into shares of our common stock at an initial conversion price equal to $0.23 per share (the "$1 Million Secured Note").

The $1 Million Secured Note bore interest at a rate of 3% per annum and had a scheduled maturity date of November 13, 2012. In order to secure our obligations under the $1 Million Secured Note, we also entered into a Security Agreement dated the Effective Date (the "Security Agreement") granting Niobe a security interest in substantially all of our personal property and assets, including our intellectual property. The $1 Million Secured Note is 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 $1 Million Secured Note will automatically be converted if (i) we raise in excess of $7.5 million of gross proceeds in an equity offering, (ii) certain milestones are achieved in our Phase 1b and RA trial of PRTX-100 in South Africa or (iii) we undertake certain fundamental transactions as defined in the $1 Million Secured Note (such as a merger, sale of all of our assets, exchange or tender offer, or reclassification of our stock or compulsory exchange). The $1 Million Secured Note also provides for the adjustment of the conversion price in the event of stock dividends and stock splits, among other items, and provides for acceleration of maturity upon an event of default (as defined in the $1 Million Secured Note).

As contemplated by the Purchase Agreement, all of our executive officers and all of the members of our 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 president and elected Kirk M. Warshaw as chief financial officer and secretary.

In addition, on the Effective Date, we terminated (i) the Investor Rights Agreement dated September 18, 2003 among us, vSpring SBIC L.P. ("vSpring") and certain of the investors set forth on Schedule A thereto (the "2003 IRA") and the Registration Rights Agreement dated May 25, 2005 among us, vSpring and certain of the investors set forth on Schedule I thereto (the "2005 RRA") in accordance with their respective terms and (ii) stock options exercisable for an aggregate of 246,714 shares of our common stock (approximately 41% of our then outstanding stock options), all of which were held by three option holders, Steven H. Kane, our former CEO, Marc L. Rose, our former CFO and vSpring.

On February 11, 2011, Niobe converted the $1 Million Secured Note, including $37,500 of accrued interest thereon, into 4,510,870 shares of our common stock.

On February 11, 2011, for the purpose of providing us with additional working capital, pursuant to our Credit Facility Agreement dated as of December 2, 2009 (the "Facility") with Niobe, we issued to Niobe a senior secured convertible promissory note, dated February 11, 2011, in the principal amount of $2,000,000, which is convertible into shares of common stock at a conversion price equal to $0.23 per share for an aggregate of 8,695,652 shares of our common stock (not including accrued interest thereon) (the "$2 Million Secured Note"). The $2 Million Secured Note bears interest at a rate of 3% per annum and matures on December 31, 2012.

Our obligations under the $2 Million Secured Note are secured by an Amended and Restated Security Agreement dated as of December 2, 2009, pursuant to which we granted Niobe a security interest in substantially all of our personal property and assets, including our intellectual property. The $2 Million Secured Note is convertible at any time, at the option of 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 Note will automatically be converted if we undertake certain Fundamental Transactions, as defined in the $2 Million Secured 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 Note also provides 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 Note.

About PRTX-100

PRTX-100 is a highly-purified form of the Staphylococcal bacterial protein known as Protein A. PRTX-100 has the ability, at very low concentrations, to bind to and to down regulate activation of human B-lymphocytes and macrophages which are the key cells mediating inflammation in certain autoimmune diseases. Laboratory studies indicate that the mechanism involves interaction with specific intracellular signaling pathways. Pre-clinical studies also demonstrate that very low doses of PRTX-100 have potent therapeutic effects in certain models of immune-mediated inflammatory diseases.

Animal Studies

Protalex's lead candidate, PRTX-100, has proven effective in two standard mouse models of autoimmunity:

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 very low doses of PRTX-100 and standard doses of Enbrel® suppressed clinical symptoms including joint swelling over the first two to three weeks of treatment, and slowed disease progression as compared with the control group. Thereafter, the PRTX-100-treated mice continued to remain disease-free whereas the mice treated with Enbrel® showed a resumption of joint inflammation and tissue damage. This response to Enbrel® was expected because the mice developed immune response to it because it is a foreign protein. Overall, these results indicate that PRTX-100 is a potential treatment for RA in humans. The data from these studies has 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 have shown no drug-related toxicity at doses up to 60-fold the proposed clinical 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 were an important component of our IND application with the FDA.

We have performed additional studies on non-human primates to determine the pharmacokinetics of PRTX-100, and to evaluate the pharmacokinetics and safety of a newer, lyophilized formulation of the drug.

Clinical Trials

Favorable pre-clinical safety and efficacy studies for our lead compound, PRTX-100, laid the foundation for the Investigational New Drug Application or IND for treating RA. We submitted the IND to the U.S. Food and Drug Administration (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 commenced our first Phase I clinical trial in December 2005 and completed the Phase I clinical trial in March 2006. This Phase I clinical trial was performed in healthy volunteers and was designed primarily to assess the safety and tolerability of PRTX-100. This study demonstrated that PRTX-100 appeared 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, CMC update, and a protocol for another Phase I clinical trial. In July and August 2007 a second Phase I study was performed under the IND, to further characterize the safety, pharmacokinetic, and pharmaco-dynamic profile of a single-dose of PRTX-100 in healthy volunteers at doses in the projected therapeutic range. Final results indicated that the drug was safe and well tolerated. A Phase 1b randomized , double-blind, placebo controlled, multiple dose, dose escalation and tolerability study of PRTX-100 in combination with methotrexate in patients with active RA in South Africa was approved in August 2009 and is currently underway.

Idiopathic Thrombocytopenic Purpura - ITP is an uncommon autoimmune bleeding disorder characterized by too few 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. This clinical study was conducted under the Australian and New Zealand Clinical Trial Notification procedure, not under US IND (the "Australian Study"). After the approval of the clinical protocol by ethics committees at six sites in Australia and one in New Zealand, the trial began enrolling patients in the second quarter of 2008. A leading Australian clinical research organization was contracted to manage and monitor this clinical trial. The Australian Study was designed to evaluate the safety and pharmacokinetics of up to four doses of PRTX-100, starting at the lowest dose, and escalating upwards after safety review of the prior dose.

The Australian Study proved extremely 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 2009. At this point further recruitment of patients was suspended. No side effects or toxicities were noted with repeated weekly doses of PRTX-100 that were not seen with single doses in healthy volunteer trials. This repeated-dose safety data formed the basis for the clinical trial application to evaluate PRTX-100 in patients with rheumatoid arthritis.

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 percent of the world's population, with prevalence rising with age to about 5% in women over 55.

PRTX-100 is modeled on an effective precedent medical device treatment approved for RA which also exposed patients to low doses of staphylococcal protein A. PRTX-100 shows measurable activity in a standard mouse model of autoimmune arthritis. Accordingly, RA is believed to represent the most likely and significant treatment indication for PRTX-100. While recent advances in biologic treatments for RA (with monoclonal antibodies) 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.

In August 2010, we commenced a multi-center Phase 1b clinical trial of PRTX-100 on adult patients with active RA in South Africa and dosed our first patient enrolled in the study. We contracted with a leading global biopharmaceutical services organization to manage and monitor this Phase 1b clinical trial. This first sequential dose escalation study in RA will enroll up to 40 patients and is expected to be completed in the fourth calendar quarter of 2011. The study has met its goals for the first three doses studied, and is currently enrolling patients into the 4th dose-escalation cohort. The trial protocol was reviewed and approved by the Medicines Control Council, the regulatory agency in South Africa. This study is not being performed under the US IND, but the clinical study report will be submitted to the IND. This is a sequential dose escalation study of the safety, pharmacokinetics, and efficacy of PRTX-100 in patients with active RA. This data could in the future support a US IND study of PRTX-100 in RA patients.

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 product formulations, stability testing and packaging of the final drug product for clinical supplies are conducted at several other FDA-approved companies in the United States. These companies have provided the drug product for both toxicological testing and clinical supplies. We believe that this entire process is scaleable to commercial production but will require additional manufacturing resources. The original three clinical trials of PRTX-100 were conducted with a liquid formulation. The current RA trial is using 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 current focus as a primary indication. RA is a serious autoimmune disorder that causes the body's immune system to mistakenly produce antibodies that attack the lining of the joints, resulting in inflammation and pain. RA can lead to joint deformity or destruction, organ damage, disability and premature death. According to a Cowen and Company, LLC report entitled "Therapeutic Categories Outlook" dated March 2009, RA affects about 1% of the U.S. population with a female to male ratio of 2 to 1 and approximately 10% of RA patients enter remission without treatment. Of the remaining 90%, one third has mild disease, one-third has moderate disease and has some response to methotrexate and one-third has significant disease and has no response to methotrexate.

RA was chosen as a target disease because it represents a well-defined, rapidly growing market for which there is no current uniformly effective treatment. It is estimated that despite treatment with current approved RA therapeutics, at least a 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. In contrast, we believe that PRTX-100 could potentially provide these patients with a choice of therapy that is efficacious, cost-effective, and has a highly favorable benefit-risk ratio.

Once further developed and approved, we believe that our products could be used to treat patients with moderate to severe cases of RA, and particularly those individuals for whom other treatments have failed. Preliminary information gained in the laboratory on the mechanism of action of PRTX-100 suggests potential efficacy in a range of autoimmune diseases, including, but not limited to psoriasis, myasthenia, ITP, and pemphigus.

Our long-term strategy, should PRTX-100 demonstrate safety and clinical proof of concept in RA, contemplates the pursuit of FDA approval to treat other autoimmune diseases where the drug's ability to decrease the inflammatory response will abrogate the underlying disease processes.

Competition

We believe, based on the pre-clinical trials and the results to date of our two Phase I clinical trials, that PRTX-100 has a potential competitive advantage as it may be safer and more efficacious than existing therapies, and will cost significantly less than competing biologic-based therapies. This potential advantage has not yet been, and may not ever be, validated in clinical trials. Current RA treatments are characterized by complex manufacturing methods and have resulted in an average annual retail cost of approximately $15,000 to $19,980 per patient, according to a Cowen and Company, LLC report entitled "Therapeutic Categories Outlook" dated March 2009. A number of pharmaceutical agents are currently being used, with varying degrees of success, to control the signs and symptoms of RA and slow its progression. Available treatment options include:

- Analgesic/anti-inflammatory preparations, ranging from simple aspirin to the COX-2 inhibitors;
- Immunosuppressive/antineoplastic drugs, including azathioprine and methotrexate;
- TNF (Tumor Necrosis Factor) inhibitors, also known as anti-TNF therapy, currently represented by etanercept (Enbrel®), infliximab (Remicade®), and adalimumab (Humira®) 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®); and
- Anti CD20 B-cell-directed therapy, rituximab (Rituxan®).

Many large and small pharmaceutical companies are active in this market, with Amgen Corporation, Johnson & Johnson, Inc. and Abbott Laboratories dominating the market for biologic therapies with their respective products, Enbrel®, Remicade® and Humira®. According to the Cowen and Company, LLC report dated March 2009 for RA in 2008 Enbrel® generated revenue of $2.09 billion; Remicade® generated revenue of $1.55 billion; and Abbot's Humira®, generated revenue of $1.38 billion. Other recent entrants into the RA market are Orencia® from Bristol-Myers Squibb and Rituxan® from Biogen Idec/Genentech which generated revenue of $360 million and $300 million for RA in 2008, respectively.

Post-marketing experience has indicated an enhanced risk for serious and opportunistic infections in patients treated with TNF inhibitors. Disseminated tuberculosis due to reactivation of latent disease was also seen commonly within clinical trials of TNF inhibitors. There is also a possibly increased risk of lymphoma in patients treated with TNF inhibitors. TNF inhibitors are not recommended in patients with demyelinating disease or with congestive heart failure. Transient neutropenia or other blood dyscrasias have been reported with Enbrel® and the other TNF inhibitors. There was also an increased risk of serious infections with rituximab therapy in clinical trials, and abatacept has also been associated with an increased risk of serious infections. Findings such as these indicate that new and safer treatments for autoimmune diseases such as RA are needed. We anticipate that PRTX-l00 and its other products will provide such opportunity, but there can be no assurance that such results will occur, pending the completion of extensive clinical trials.

As mentioned above, several companies have marketed or are developing thrombopoetin agonists for treatment of ITP. They include Amgen's Nplate and GSK's Promacta, both now FDA approved, and Ligand Pharmaceutical's LGD4665 currently in clinical trials.

Government Regulation and Product Approval

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

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

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

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

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

Clinical Trials

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

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

- *Phase II clinical trials* are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the drug candidate for specific targeted indications and to determine an optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials. In some cases, a sponsor may decide to conduct what is referred to as a "Phase IIb" evaluation, which is a second, confirmatory Phase II clinical trial that could, if positive and accepted by the FDA, serve as a pivotal clinical trial in the approval of a drug candidate.

- *Phase III clinical trials* are commonly referred to as pivotal trials. When Phase II clinical trials demonstrate that a dose range of the drug candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.

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

Biological License Application

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

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

Orphan Drug Designation and Exclusivity

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

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

Fast Track Designation

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

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

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

- *Priority Review.* As explained above, a drug candidate may be eligible for a six-month priority review. The FDA assigns priority review status to an application if the drug candidate provides a significant improvement compared to marketed drugs in the treatment, diagnosis or prevention of a disease. A fast track drug would ordinarily meet the FDA's criteria for priority review, but may also be assigned a standard review. We do not know whether any of our drug candidates will be assigned priority review status or, if priority review status is assigned, whether that review or approval will be faster than conventional FDA procedures, or that the FDA will ultimately approve the drug.

- *Accelerated Approval.* Under the FDA's accelerated approval regulations, the FDA is authorized to approve drug candidates that have been studied for their safety and efficacy in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit to patients over existing treatments based upon either a surrogate endpoint that is reasonably likely to predict clinical benefit or on the basis of an effect on a clinical endpoint other than patient survival or irreversible morbidity. In clinical trials, surrogate endpoints are alternative measurements of the symptoms of a disease or condition that are substituted for measurements of observable clinical symptoms. A drug candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase IV or post-approval clinical trials to validate the surrogate endpoint or confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies with due diligence, or to validate a surrogate endpoint or confirm a clinical benefit during post-marketing studies, may cause the FDA to seek to withdraw the drug from the market on an expedited basis. All promotional materials for drug candidates approved under accelerated regulations are subject to prior review by the FDA

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

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

Other Regulatory Requirements

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

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

Foreign Regulation

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

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

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

Patents, Trademarks, and Proprietary Technology

Our success will also depend on our ability to maintain trade secrets and proprietary technology in the United States and in other countries, and to obtain and maintain patents for our bioregulatory technology. We filed an initial usage patent application with the U.S. Patent and Trademark Office or PTO, in April 2002. In October 2006, the PTO notified us of the allowance of the patent and in May 2007, the PTO issued U.S. Patent #7,211,258. In November 2006, we filed a further usage patent application with the PTO for PRTX-100 and in October 2010, the PTO issued U.S. patent #7,807,170. We have also filed for foreign protection relating to this patent in Canada, Japan and the European Union. In December 2010, we were informed that the Japan Patent Office approved our patent application and issued Japanese Letters Patent, Japanese patent #4598404. The Japanese patent has an expiration date of March 6, 2023.

Employees

We have three part-time employees, our president, our chief financial officer and an administrative person. In addition, 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 2 to the financial statements describes the significant accounting policies and methods used in the preparation of our financial statements.

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

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

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

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

Research and Development Expenses - Research and Development expenses ("R&D Expenses") were $354,092 and $330,770 for the three months ended August 31, 2011 and 2010, respectively. The increase in R&D Expenses for the three month period ended August 31, 2011 was primarily the result of activities associated with the aforementioned clinical trial in South Africa.

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 $178,589 and $113,164, for the three months ended August 31, 2011 and 2010, respectively. The increase in Administrative expenses for the three month period ended August 31, 2011 compared to the same prior year period was due to increased employee stock compensation.

Professional Fees - Professional expenses were $65,836 and $ $68,631 for the three months ended August 31, 2011 and 2010, respectively. The decrease for the three month period ended August 31, 2011 was primarily due to a decrease in consulting expenses as compared to the same period last year.

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 August 31, 2011 was $51,842,303 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. We have issued shares in private placements at discounts to then current market price.

On September 18, 2003, we raised $12,657,599 through the sale of 1,489,129 shares of our common stock at $8.50 per share, with warrants to purchase an additional 632,879 shares of our common stock, at an exercise price of $12.00 per share. These warrants expired on September 19, 2008. Net of transaction costs of $1,301,536, our proceeds were $11,356,063.

On May 25, 2005, we raised $5,057,885 through the sale of 518,757 shares of our common stock at $9.75 per share, with warrants to purchase an additional 184,024 shares of our common stock, at an exercise price of $11.25 per share. All of these warrants expired on May 25, 2010. Net of transaction costs of $206,717, our proceeds were $4,851,168.

On December 30, 2005, we raised $5,839,059 through the sale of 519,026 shares of our common stock at $11.25 per share, with warrants to purchase an additional 129,757 shares of our common stock, at an exercise price of $14.95 per share. We also issued warrants to purchase 45,415 shares of our common stock, at an exercise price of $14.95 per share, to the placement agent. All of these warrants expired on December 30, 2010. Net of transaction costs of approximately $328,118, our proceeds were $5,510,941.

In the fourth fiscal quarter of 2006, existing investors exercised 70,320 warrants which resulted in $786,538 in cash proceeds.

On July 7, 2006, we raised $14,217,660, net of transaction costs of $959,874, through the sale of 1,214,203 shares of our common stock at $12.50 per share, with warrants to purchase an additional 303,551 shares of our common stock, at an exercise price of $19.25 per share. We also issued warrants to purchase 106,243 shares of our common stock, at an exercise price of $19.25 per share, to the placement agent. All of these warrants expire on July 7, 2011.

In the first fiscal quarter of 2007, existing investors and option holders exercised 26,700 warrants and 1,200 options which resulted in $315,574 in cash proceeds.

On November 11, 2009, we raised $3,000,000; $2,000,000 from the sale of common stock and $1,000,000 from the issuance the $1 Million Secured Note to Niobe.

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 Note.

As of the date of this Report, all of our previously outstanding warrants have expired.

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

Our operating cash outflows for the three months ended August 31, 2011 and 2010 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 August 31, 2011, 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 (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 period 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
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act*
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act*
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act*
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act*
101.INS **	XBRL Instance Document
101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document.

* Filed herewith

** Filed with this report in accordance with Rule 406T of Regulation S-T, the information in these exhibits shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to liability under that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

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: September 28, 2011

PROTALEX, INC.

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

Date: September 28, 2011

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: September 28, 2011

/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: September 28, 2011

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

Exhibit 32.1

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

In connection with the quarterly report of Protalex, Inc. (the "Company") on Form 10-Q for the period ending August 31, 2011 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: September 28, 2011

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

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

Exhibit 32.2

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

In connection with the quarterly report of Protalex, Inc. (the "Company") on Form 10-Q for the period ending August 31, 2011 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: September 28, 2011

/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.