

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

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FORM 10-Q

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

For the quarterly period ended August 31, 2009

OR

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

Commission File Number: 000-28385

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**Protalex, Inc.**  
(Exact Name of Registrant as Specified in its Charter)

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**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**91-2003490**  
(I.R.S. Employer  
Identification Number)

**145 Union Square Drive**  
**New Hope, PA 18938**  
(Address of Principal Executive Offices and Zip Code)

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

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

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

Indicate by check mark 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 October 12, 2009: 28,600,464 shares.

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**Protalex, Inc.**

**FORM 10-Q**

**August 31, 2009**

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**PART I - FINANCIAL INFORMATION**

**ITEM 1. FINANCIAL STATEMENTS**

PROTALEX, INC.  
(A Company in the Development Stage)

**BALANCE SHEETS**

	<u>August 31,</u> <u>2009</u>	<u>May 31,</u> <u>2009</u>
	(Unaudited)	
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,866,272	\$ 2,637,292
Prepaid expenses	<u>225,462</u>	<u>193,757</u>
Total current assets	<u>2,091,734</u>	<u>2,831,049</u>
<b>PROPERTY &amp; EQUIPMENT:</b>		
Lab equipment	327,287	327,287
Office and computer equipment	195,987	195,987
Furniture & fixtures	40,701	40,701
Leasehold improvements	<u>89,967</u>	<u>89,967</u>
	653,942	653,942
Less accumulated depreciation and amortization	<u>(632,982)</u>	<u>(628,780)</u>
	<u>20,960</u>	<u>25,162</u>
<b>OTHER ASSETS:</b>		
Deposits	7,990	7,990
Intellectual technology property, net of accumulated amortization of \$10,008 and \$9,753 as of August 31, 2009 and May 31, 2009, respectively	<u>10,292</u>	<u>10,547</u>
Total other assets	<u>18,282</u>	<u>18,537</u>
Total Assets	<u>\$ 2,130,976</u>	<u>\$ 2,874,748</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable	\$ 363,674	\$ 398,734
Payroll and related liabilities	909,032	1,185,638
Accrued expenses	—	8,057
Deferred rent	<u>743</u>	<u>1,192</u>
Total liabilities	1,273,449	1,593,621
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, par value \$0.00001, 100,000,000 shares authorized; 28,600,464 shares issued and outstanding	286	286
Additional paid in capital	45,925,023	45,865,352
Deficit accumulated during the development stage	<u>(45,067,782)</u>	<u>(44,584,511)</u>
Total stockholders' equity	<u>857,527</u>	<u>1,281,127</u>
Total liabilities and stockholders' equity	<u>\$ 2,130,976</u>	<u>\$ 2,874,748</u>

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

PROTALEX, INC.  
(A Company in the Development Stage)

**STATEMENTS OF OPERATIONS**

For the three month period ended August 31, 2009 and 2008 and  
From Inception (September 17, 1999) through August 31, 2009  
(Unaudited)

	<b>Three Months Ended August 31, 2009</b>	<b>Three Months Ended August 31, 2008</b>	<b>From Inception Through August 31, 2009</b>
Revenues	\$ —	\$ —	\$ —
<b>Operating Expenses</b>			
Research and development (including depreciation and amortization)	(193,265)	(1,021,498)	(27,947,049)
Administrative (including depreciation and amortization)	(146,190)	(631,831)	(15,760,827)
Professional fees	(143,129)	(169,587)	(3,388,263)
Depreciation and amortization	<u>(1,019)</u>	<u>(1,085)</u>	<u>(164,835)</u>
Operating loss	(483,603)	(1,824,001)	(47,260,974)
<b>Other income (expense)</b>			
Interest income	332	39,051	2,196,210
Interest expense	—	—	(70,612)
Gain on disposal of equipment, net	<u>—</u>	<u>78,174</u>	<u>67,594</u>
Net loss	<u>\$ (483,271)</u>	<u>\$ (1,706,776)</u>	<u>\$ (45,067,782)</u>
Weighted average number of common shares outstanding	28,600,464	28,600,464	18,650,682
Loss per common share – basic and diluted	\$ (.02)	\$ (.06)	\$ (2.42)

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

PROTALEX, INC.  
(A Company in the Development Stage)

**STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY**

From Inception (September 17, 1999) through August 31, 2009  
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated During The Development Stage	Total
September 17, 1999 — initial issuance of 10,000 shares for intellectual technology license at \$.03 per share	10,000	\$ 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 84 shares to individual for \$25,000	84	25,000	—	—	—	25,000
November 15, 1999 — reverse merger transaction with Enerdyne Corporation, net transaction amounts	8,972,463	118,547	—	(118,547)	—	—
November 18, 1999 — February 7, 2000 — issuance of 459,444 shares to various investors at \$0.36 per share	459,444	165,400	—	—	—	165,400
January 1, 2000 — issuance of 100,000 shares in exchange for legal services	100,000	15,000	—	—	—	15,000
May 1 - 27, 2000 — issuance of 640,000 shares to various investors at \$1.00 per share	640,000	640,000	—	—	—	640,000
May 27, 2000 — issuance of 1,644 shares to an individual in exchange for interest Due	1,644	1,644	—	—	—	1,644
Net loss for the year ended May 31, 2000	—	—	—	—	(250,689)	(250,689)
Balance, May 31, 2000	10,183,635	965,891	—	(368,547)	(250,689)	346,655
December 7, 2000 — issuance of 425,000 shares to various investors at \$1.00 per share	425,000	425,000	—	—	—	425,000
May 31, 2001 — Forgiveness of debt owed to shareholder	—	—	40,000	—	—	40,000
Net loss for the year ended May 31, 2001	—	—	—	—	(553,866)	(553,866)
Balance, May 31, 2001	10,608,635	1,390,891	40,000	(368,547)	(804,555)	257,789

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

PROTALEX, INC.  
(A Company in the Development Stage)

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

From Inception (September 17, 1999) through February 28, 2009  
(Unaudited)

	Common Stock		Additional	Common	Deficit	Total
	Shares	Amount	Paid in	Stock-	Accumulated	
			Capital	Contra	During The	
					Development	
					Stage	
August 13, 2001 — Contribution by Shareholders	—	—	143,569	—	—	\$ 143,569
November 7, 2001 — issuance of 881,600 Shares at \$1.25 per share	881,600	\$ 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	11,490,235	2,492,891	316,569	(368,547)	(2,085,020)	355,893
July 5, 2002 — issuance of 842,000 shares at \$1.50 per share	842,000	1,263,000	—	—	—	1,263,000
July 1, 2002 - May 1, 2003 – purchase of common stock from shareholder at \$.70 per share	(130,955)	(91,667)	—	—	—	(91,667)
January 15, 2003 - May 15, 2003 — common stock issued to Company president	41,670	82,841	—	—	—	82,841
May 14, 2003 — common stock issued to employee	5,000	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	12,247,950	3,758,315	603,912	(368,547)	(3,750,110)	243,570
June 15, 2003, common stock issued to Company president	8,334	16,418	—	—	—	16,418
June 15, 2003, purchase of common stock from shareholder	(12,093)	(8,333)	—	—	—	(8,333)
September 18, 2003 – issuance of 7,445,646 of common stock issued in private placement At \$1.70 per share, net of transaction costs	7,445,646	11,356,063	—	—	—	11,356,063
September 19, 2003 – repurchase and retired 2,994,803 shares for \$300,000	(2,994,803)	(300,000)	—	—	—	(300,000)
December 12, 2003 – issuance of 39,399 shares to terminated employees at \$2.60 per share	39,399	102,438	—	—	—	102,438
March 1, 2004 – common stock issued to employee at \$2.55 per share	50,000	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 this financial statement.*

PROTALEX, INC.  
(A Company in the Development Stage)

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

From Inception (September 17, 1999) through February 28, 2009  
(Unaudited)

	Common Stock		Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated During The Development Stage	Total
	Shares	Amount				
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	16,784,433	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 \$2.55 per share	15,000	38,250	—	—	—	38,250
February 28, 2005 – Reclass Par Value for Reincorporation into DE as of 12/1/04	—	(14,701,935)	14,701,935	—	—	0
May 25, 2005 - issuance of 2,593,788 shares of common stock issued in private placement At \$1.95 per share, net of transaction costs	2,593,788	25	4,851,168	—	—	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	19,393,221	194	20,913,822	—	(12,307,203)	8,606,813
August 23, 2005 – common stock issued to employee	40,000	0	100,000	—	—	100,000
October 19, 2005 – common stock issued to employee	10,000	0	25,000	—	—	25,000
December 30, 2005 – issuance of 2,595,132 shares of common stock issued in private placement at \$2.25 per share, net of transaction costs	2,595,132	26	5,510,941	—	—	5,510,967
June 1, 2005 – May 31, 2006 – warrants exercised	351,598	4	786,534	—	—	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	22,389,951	224	27,740,976	—	(18,411,605)	9,329,595

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

PROTALEX, INC.  
(A Company in the Development Stage)

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

From Inception (September 17, 1999) through February 28, 2009  
(Unaudited)

	Common Stock		Additional Paid in Capital	Common Stock- Contra	Deficit Accumulated During The Development Stage	Total
	Shares	Amount				
July 7, 2006 – issuance of 6,071,013 shares of common stock issued in private placement at \$2.50 per share, net of transaction costs	6,071,013	61	14,217,660	—	—	14,217,721
June 1, 2006 – May 31, 2007 – warrants exercised	133,500	1	300,373	—	—	300,374
June 1, 2006 – May 31, 2007 – stock options exercised	6,000	0	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	28,600,464	286	44,101,059	—	(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	28,600,464	286	45,112,084	—	(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	<u>28,600,464</u>	<u>\$ 286</u>	<u>\$45,865,352</u>	<u>\$ —</u>	<u>\$ (44,584,511)</u>	<u>\$ 1,281,127</u>
June 1, 2009 – August 31, 2009 – shared-based compensation to board members, employees and consultants	—	—	59,671	—	—	59,671
Net loss for the three months ended August 31, 2009	—	—	—	—	(483,271)	(483,271)
Balance, August 31, 2009	<u>28,600,464</u>	<u>\$ 286</u>	<u>\$45,925,023</u>	<u>\$ —</u>	<u>\$ (45,067,782)</u>	<u>\$ 857,527</u>

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



PROTALEX, INC.  
(A Company in the Development Stage)

**STATEMENTS OF CASH FLOWS**

For the three month periods ended August 31, 2009 and 2008 and  
From Inception (September 17, 1999) through August 31, 2009  
(Unaudited)

	<b>Three Months Ended August 31, 2009</b>	<b>Three Months Ended August 31, 2008</b>	<b>From Inception Through August 31, 2009</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (483,271)	\$ (1,706,776)	\$ (45,067,782)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities			
(Gain) on disposal of equipment, net	—	(78,174)	(67,594)
Depreciation and amortization	4,457	36,318	909,159
Share based compensation expense	59,671	176,565	5,716,339
Non cash expenses	—	—	16,644
(Increase)/decrease in:			
Prepaid expenses and deposits	(31,705)	(3,919)	(233,452)
Increase/(decrease) in:			
Accounts payable and accrued expenses	(43,117)	(389,944)	363,674
Payroll and related liabilities	(276,606)	(15,328)	909,032
Other liabilities	(449)	(248)	743
Net cash and cash equivalents used in operating activities	<u>(771,020)</u>	<u>(1,981,506)</u>	<u>(37,453,237)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Acquisition of intellectual technology license – fee portion	—	—	(20,000)
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	—	200,000	206,000
Net cash and cash equivalents provided by (used in) investing activities	<u>—</u>	<u>200,000</u>	<u>(969,936)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from stock issuance, including options and warrants exercised	—	—	40,658,458
Principal payment on equipment notes payable and capital leases	—	—	(295,411)
Contribution by shareholders	—	—	183,569
Principal payment on note payable to individuals	—	—	(225,717)
Issuance of note payable to individuals	—	—	368,546
Acquisition of common stock	—	—	(400,000)
Net cash and cash equivalents provided by financing activities	<u>—</u>	<u>—</u>	<u>40,289,445</u>
<b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(771,020)</b>	<b>(1,781,506)</b>	<b>1,866,272</b>
Cash and cash equivalents, beginning	<u>2,637,292</u>	<u>8,442,809</u>	<u>—</u>
Cash and cash equivalents, ending	<u>\$ 1,866,272</u>	<u>\$ 6,661,303</u>	<u>\$ 1,866,272</u>
<b>SUPPLEMENTAL SCHEDULE OF CASH FLOW INFORMATION:</b>			
Interest paid	\$ —	\$ —	\$ 66,770
Taxes paid	\$ —	\$ —	\$ 100

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

PROTALEX, INC.  
(A Company in the Development Stage)

**NOTES TO UNAUDITED FINANCIAL STATEMENTS**

From Inception (September 17, 1999) through August 31, 2009

**NOTE 1. NOTES TO INTERIM FINANCIAL STATEMENTS**

The interim financial data 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 Protalex, Inc. (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 filed as part of the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2009. This quarterly report should be read in conjunction with such annual report.

As of the date of this Report, the Company has no employees and has insufficient funds to cover future clinical trials and Chemistry, Manufacturing and Control or CMC related expenses. As of the date of this Report, the Company has ceased or suspended all operations. These matters raise substantial doubt about the ability of the Company to continue as a 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. Additional financing or potential sublicensing of PRTX-100 will be required in order to restart operations. As a result, our independent registered public accounting firm, Grant Thornton LLP, indicated in their report on our 2009 financial statements that there is substantial doubt about our ability to continue as a going concern. The Company is a development stage enterprise and does not anticipate generating operating revenue for the foreseeable future. The ability of the Company to continue as a going concern is dependent upon raising sufficient funds to continue the development of PRTX-100 through the regulatory process. 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.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Estimates**

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

**Loss per Common Share**

The Financial Accounting Standards Board (FASB) has issued Statement of Financial Accounting Standards No. 128, "Earnings Per Share" (SFAS No. 128). SFAS No. 128 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 shareholders 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, 2009 and 2008, the Company had potentially dilutive securities consisting of warrants and stock options totaling 6,959,389 comprised of 3,928,896 warrants and 3,030,493 stock options and 12,448,206 comprised of 6,601,380 warrants and 5,846,826 stock options, respectively.

## Share Based Compensation

Effective June 1, 2006, the Company adopted the fair value recognition provisions of Statement of Financial Accounting Standard No. 123 (revised), Accounting for Share-Based Payment (“SFAS No. 123R”) 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, compensation cost included in operating expenses was \$59,671 and \$176,565 for the three months ended August 31, 2009 and 2008, respectively and 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 of SFAS No. 123R, prior period results were 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 to date 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”) No. 107 “Valuation of Share-Based Payment Arrangements for Public Companies”, and No. 110, Share-Based Payment, in connection with the adoption of SFAS No. 123R.

Prior to the adoption of SFAS No. 123R, the Company accounted for stock options granted to employees using the intrinsic value method under the guidance of APB No. 25, and provided pro forma disclosure as required by SFAS No. 123. Stock options issued to non-employees were accounted for as required by SFAS No. 123. Options to non-employees were accounted for using the fair value method, which recognizes the value of the option as an expense over the related service period with a corresponding increase to additional paid-in capital.

The Board of Directors adopted and the stockholders approved the 2003 Stock Option Plan in 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 4,500,000 shares reserved for grants of options under the plan, of which 1,677,571 have been issued and 4,000 were exercised. The Company has issued 1,358,922 stock options as stand alone grants, of which 2,000 were exercised prior to the adoption of the 2003 Stock Option Plan. 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.

SFAS No. 123R 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 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 the “simplified method” for plain vanilla options as allowed by SAB No. 107 and as further permitted by SAB No. 110. 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 over the option’s expected term. 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, 2009, there were 3,030,493 stock options outstanding. At August 31, 2009, the aggregate unrecognized compensation cost of unvested options, as determined using a Black-Scholes option valuation model was approximately \$484,000 (net of estimated forfeitures) and will be recognized over a weighted average period of 0.84 years. During the three months ended August 31, 2009, the Company granted no stock options and 266,319 options were forfeited or expired, respectively.

	<b>Three Months Ended August 31, 2009</b>	<b>Three Months Ended August 31, 2008</b>	<b>From Inception through August 31, 2009</b>
Dividends per year	—	0	0
Volatility percentage	—	96%	90%-112%
Risk free interest rate	—	3.51%	2.07%-5.11%
Expected life (years)	—	6.25-10	3-10
Weighted average fair value	—	\$ .41	\$ 1.56

The following summarizes certain information regarding stock options as of and for the period ended August 31, 2009:

	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>
Outstanding at May 31, 2009	3,296,812	\$ 1.57	6.0
Granted	—	—	—
Exercised	—	—	—
Forfeited	(115,627)	\$ 0.86	—
Expired	(150,692)	\$ 1.43	—
Outstanding at August 31, 2009	<u>3,030,493</u>	\$ 1.61	5.5
Exercisable at August 31, 2009	<u>2,414,545</u>	\$ 1.80	5.5

The outstanding and exercisable stock options as of August 31, 2009 had an intrinsic value of \$0 and \$0, respectively.

<b>Exercise Price Range</b>	<b>Number</b>	<b>Total</b>		<b>Exercisable</b>	
		<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Life (years)</b>	<b>Number</b>	<b>Weighted Average Remaining Life (years)</b>
\$0.00 – 0.45	500,000	\$ 0.45	8.9	135,427	\$ 0.45 8.9
\$0.46 – 0.90	150,000	\$ 0.85	9.0	37,500	\$ 0.85 9.0
\$0.91 – 1.35	200,000	\$ 1.23	5.3	139,590	\$ 1.24 5.3
\$1.36 – 1.80	1,256,922	\$ 1.50	3.3	1,256,922	\$ 1.50 3.3
\$1.81 – 2.25	92,000	\$ 2.13	5.0	89,374	\$ 2.13 5.0
\$2.26 – 2.70	550,000	\$ 2.50	6.0	495,831	\$ 2.52 6.0
\$2.71 – 3.15	281,571	\$ 2.87	6.6	259,901	\$ 2.87 6.6
	<u>3,030,493</u>	\$ 1.61	5.5	<u>2,414,545</u>	\$ 1.80 5.5

### NOTE 3. LIQUIDITY

Since inception, the Company has incurred an accumulated deficit of \$45,067,782 through August 31, 2009. As of August 31, 2009, the Company had cash and cash equivalents of \$1,866,272 and net working capital of \$818,285. 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 the continued development efforts relating to PRTX-100. As of the date of this Report, the Company has no employees and has insufficient funds to cover future clinical trials and CMC related expenses. As of the date of this Report, the Company has suspended or ceased all operations. These matters raise substantial doubt about the ability of the Company to continue as a going concern.

Additional financing or potential sublicensing of PRTX-100 will be required in order to restart and continue operations. The most likely sources of additional financing include the private sale of the Company's equity or debt securities, including bridge loans to the Company from third party lenders. Additional capital that is required by the Company may not be available on reasonable terms, or at all.

#### **NOTE 4. RECENT ACCOUNTING PRONOUNCEMENTS**

In June 2009, the FASB issued SFAS No. 168, The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement No.162 (“SFAS 168”). SFAS 168 establishes the FASB Accounting Standards Codification as the single source of authoritative US generally accepted accounting principles recognized by the FASB to be applied to nongovernmental entities. SFAS 168 is effective for financial statements issued for interim and annual periods ending after September 15, 2009. The adoption of SFAS 168 will not have an impact on the Company's financial position, results of operations or cash flow. The Company will update the disclosures for the appropriate FASB codification reference after adoption in the second quarter of fiscal 2010.

In May 2009, the FASB issued SFAS No. 165, *Subsequent Events* (“SFAS 165”). SFAS 165 is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. It requires the disclosure of the date through which an entity has evaluated subsequent events and the basis for selecting that date, that is, whether that date represents the date the financial statements were issued or were available to be issued. SFAS 165 is effective for interim or annual financial periods ending after June 15, 2009. The Company has evaluated subsequent events after the balance sheet date of August 31, 2009 through the date this quarterly report is filed on October 15, 2009.

In December 2007, the FASB issued SFAS No. 141R (revised 2007) *Business Combinations* (“SFAS 141R”). SFAS 141R states that all business combinations (whether full, partial or step acquisitions) will result in all assets and liabilities of an acquired business being recorded at their fair values. Certain forms of contingent considerations and certain acquired contingencies will be recorded at fair value at the acquisition date. SFAS 141R also states acquisition costs will generally be expensed as incurred and restructuring costs will be expensed in periods after the acquisition date. This statement is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company adopted SFAS 141R on June 1, 2009. The adoption did not have a material impact on its financial statements.

In December 2007, the FASB ratified the Emerging Issue Task Force (“EITF”) Issue 07-01, *Accounting for Collaborative Arrangements* (“EITF 07-01”). EITF 07-01 clarifies the accounting for contractual arrangements wherein two or more parties come together to participate in a joint operating activity which is conducted based on provisions of a contract. EITF 07-01 provides guidance on income statement classification of revenues and expenses related to such activities, and specifies disclosures that should be made with respect to such activities. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. The Company adopted EITF 07-01 on June 1, 2009. The adoption did not have a material impact on its financial statements.

#### **NOTE 5. RELATED PARTIES**

For the three month period ended August 31, 2009, the Company incurred \$0 of expenses related to air travel to a partnership principally owned by the Chief Executive Officer of the Company. For the three month period ended August 31, 2008, the Company incurred \$1,758 of expenses related to air travel to a partnership principally owned by the Chief Executive Officer of the Company.

The Company had an agreement with its Chairman to pay \$12,500 per month as a director fee which was terminated effective as of April 1, 2009 as described below. For the three month period ended August 31, 2009, the Company incurred \$0, for this director's fee. For the three month period ended August 31, 2008, the Company incurred \$37,500, for this director's fee.

The Company had an agreement with Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro to pay each \$1,667 per month payable on a quarterly basis in arrears as a director fee which agreement for each director was terminated effective as of April 1, 2009 as described below. For the three month periods ended August 31, 2009, the Company incurred \$0 for these directors' fees. For the three month periods ended August 31, 2008, the Company incurred \$21,668 for these directors' fees.

Pursuant to a Cash Waiver & Option Termination Agreement dated April 10, 2009, each of the outside Directors of the Company, G. Kirk Raab, Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro who were entitled to a Director's cash fee agreed to waive all such accrued and unpaid Director cash fees and terminate any rights for further cash fees. For Mr. Raab, those cash fees ceased as of April 1, 2009. For the other Directors, those cash fees ceased as of February 1, 2009. In addition, each of these Directors agreed to terminate immediately all of their existing stock options in the Company (vested and unvested).

As previously disclosed in our Form 10-K filed on August 28, 2009, Messers. Kane and Rose have voluntarily terminated their employment. Messers. Kane and Rose remain the CEO and CFO, respectively, of the Company. As of the date of this Report, while Mr. Rose has not accepted full time employment elsewhere, Mr. Kane is now currently also the Chairman and CEO of Patient Safety Technologies, Inc. At May 31, 2009, the Company accrued \$845,406 for the Company's severance obligations to Messers. Kane and Rose covering salary, payroll taxes and health benefits. As also disclosed on our Form 8-K dated July 2, 2009, the Company subsequently entered into a consulting agreement with Mr. Rose providing for certain consulting fees.

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

The following discussion should be read in conjunction with the Company's unaudited financial statements and related notes included in Item 1, "Financial Statements," of this Quarterly Report on Form 10-Q, as well as the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2009. This discussion, as well as the remainder of this Quarterly Report on Form 10-Q, may contain forward-looking statements that are not historical facts and that are intended to be covered by the safe harbor for forward-looking statements provided by the Private Securities Litigation Reform Act of 1995. Forward looking statements can be identified by the use of words such as "believe," "expect," "may," "will," "should," "intend," "anticipate" or the negative thereof or comparable terminology, and include discussions of matters such as anticipated financial performance, liquidity and capital resources, business prospects, technological developments, new and existing products, regulatory approvals and research and development activities. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expected. Please see the Company's Annual Report on Form 10-K for the fiscal year ended May 31, 2009 and other documents filed with the Securities and Exchange Commission for additional disclosures regarding potential risk factors that may cause the Company's actual results and experience to differ materially from those contained in such forward-looking statements.

### **Overview**

As of the date of this Report, the Company has no employees and insufficient funds to cover future clinical trials and Chemistry, Manufacturing and Control or CMC related expenses. The Company has suspended or ceased all operations.

These matters raise substantial doubt about the ability of the Company to continue as a going concern.

We are a development stage company which has been engaged in developing a class of biopharmaceutical drugs for treating autoimmune and inflammatory diseases. Our lead product, PRTX-100, has demonstrated effectiveness in pre-clinical studies in regulating the immune system with persisting effects. 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 clinical trials. We currently have no product on the market. We initially targeted the autoimmune diseases idiopathic thrombocytopenic purpura, or ITP and rheumatoid arthritis, or RA.

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 United States Food and Drug Administration or 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 with 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. The basic safety data demonstrated that PRTX-100 was safe and well tolerated. There were no deaths or serious adverse events. The pharmacokinetic (PK) profile was favorable and the pre-clinical PK data were confirmed by the data in this Phase I clinical trial. 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.

RA is an autoimmune disease that causes the inflammation of the membrane lining multiple joints, resulting in pain, stiffness, warmth, redness and swelling. The inflamed joint lining, the synovium, can invade and damage bone and cartilage. Inflammatory cells release enzymes and cytokines that may damage bone and cartilage. The involved joint can lose its shape and alignment, resulting in pain and loss of movement. In July 2007, we commenced with an additional Phase I clinical trial designed to gain more detailed information on biomarkers, including gene expression profiling and platelet functional assessments which will allow for more optimized patient selection and targeting in the upcoming clinical trials. This second Phase I clinical trial extended the clinical investigation of PRTX-100 tolerability, PK, and pharmacodynamics, or PD, at higher dose ranges. Dosing was completed in July 2007 and final results indicated that the drug was safe and well tolerated. A Phase Ib randomized, double-blind, placebo-controlled, multiple dose, dose escalation safety and tolerability study of PRTX-100 in combination with methotrexate in patients with active RA in South Africa has been approved.

ITP is an uncommon autoimmune bleeding disorder characterized by too few platelets in the blood. Affected individuals may have bruising, small purple marks on the skin called petechiae, bleeding from the gums after having dental work, nosebleeds or other bleeding that is hard to stop, and in women, heavy menstrual bleeding. Although bleeding in the brain is rare, it can be life threatening if it occurs. The affected individuals make antibodies against their own platelets leading to the platelets' destruction, which in turn leads to the abnormal bleeding. In ITP, we contracted Trident Clinical Research Pty Ltd, a leading Australian clinical research organization, to manage and monitor our first-in-patient ITP clinical trial. This clinical trial is designed to provide initial multiple dose safety and PK data as well as preliminary efficacy information. We have been approved for six sites in Australia and one in New Zealand, all regional referral centers for treatment of chronic ITP, to conduct a repeated dose study of PRTX-100 in chronic ITP patients. This clinical trial began enrolling patients in the second calendar quarter of 2008. In calendar 2008, we enrolled nine patients of which five completed the trial and final results indicated that the drug was safe and well tolerated, although no efficacy data was obtained. Subsequently, the Company obtained protocol approval to increase the dose range. While the Company was actively soliciting patients in calendar 2009 under this new protocol, no patients have been enrolled and none are currently being solicited as of the date of this Report.

As of the date of this Report, the Company has terminated further recruitment of patients for its ITP clinical trials pending the raising of additional funding, the retention of additional clinical personnel and an evaluation of the Company's clinical trial programs.

Our bioregulatory compounds are based on the principle of normalizing the activities of immune cells at a more basic level than traditional pharmaceutical agents, which act upon the end products of complex body functions. In autoimmune disease models, PRTX-100, which is a natural compound, has reversed the pathologic process resulting in a restoration and maintenance of normal healthy tissue. This biotechnology could be applied to a range of serious autoimmune diseases that affect millions of sufferers worldwide, such as pemphigus, systemic lupus erythematosus or lupus, psoriasis, inflammatory bowel diseases such as Crohn's disease and ulcerative colitis, insulin-dependent diabetes mellitus, and multiple sclerosis. To date, however, we have not conducted any pre-clinical trials related to the treatment of these diseases and to do so would require substantial additional capital infusions.

Our business and laboratory operations were located in New Hope, Pennsylvania where we continue to maintain our lease. We previously outsourced all of our activities to contract organizations and facilities. For example, we previously refined the manufacturing process of PRTX-100 under Current Good Manufacturing Practice, or cGMP. With all of our operations suspended or ceased, the Company runs the risk of a significant delay in commencing future clinical trial programs due to the lack of adequate clinical trial material.

Our in-house research previously included demonstrating the efficacy of PRTX-100 in well established and characterized animal models of RA and other autoimmune diseases. For example, we have tested PRTX-100 in the murine collagen induced arthritis model, or CIA, which is considered to be a predictive efficacy model for RA in humans. This is the model that was used to test the efficacy of the FDA approved drug, etanercept, or Enbrel®. PRTX-100 has also demonstrated its efficacy in an animal model of systemic lupus erythematosus. Additionally, our laboratory personnel have developed a pre-clinical ITP model with data showing that PRTX-100 inhibits the phagocytosis (ingestion) of platelets in vitro. Platelet phagocytosis is the effector limb of ITP.

We have concluded eight private placements of our common stock, raising a total of \$42.2 million in the aggregate and carrying us through basic research, pre-clinical and early stage clinical trials. The private placement in July 2006 raised approximately \$15.2 million. We have completed two Phase I clinical trials, commenced with the Phase Ib clinical trial for ITP in Australia which as of the date of this Report has been terminated and previously commenced the planning process for a Phase Ib clinical trial for RA in South Africa, which planning process is currently suspended. Without adequate additional financing, however, the Company will be unable to restart and fund a continuance of the FDA approval process.

### **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 SFAS No. 123R, Share-Based Payments ("SFAS 123R"). SFAS 123R 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 SFAS 123R, 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 SFAS 123R. Prior to the adoption of SFAS 123R, we accounted for our stock option grants under the provisions of Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees ("APB25") and made pro forma footnote disclosures as required by SFAS No. 148, Accounting for Stock-Based Compensation—Transition and Disclosure, which amends SFAS No. 123, Accounting for Stock-Based Compensation.

## Results of Operations

*Research and Development Expenses* - - Research and Development expenses were \$193,265 and \$1,021,498 for the three months ended August 31, 2009 and 2008, respectively. The decrease of \$828,233, or 81%, for the three month period was primarily the result of decreased employee compensation and share based compensation expense and a decrease in product manufacturing, formulation and packaging related costs as compared to the same period last year.

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 \$146,190, and \$631,831 for the three months ended August 31, 2009 and 2008, respectively. The decrease of \$485,641, or 77%, for the three month period was due to decreased employee compensation and share based compensation expense as compared to the same periods last year.

*Professional Fees* - Professional expenses were \$143,129, and \$169,587, for the three months ended August 31, 2009 and 2008. The decrease of \$26,458, or 16%, for the three month period was due to a decrease in legal, accounting, and consulting fees as compared to the same period last year.

*Interest income* - Interest income was \$332, and \$39,051, for the three months ended August 31, 2009 and 2008, respectively. The decrease of \$38,719, or 99%, for the three month period was attributed to a decrease in interest bearing cash balances resulting from the use of cash in operations and lower interest rates as compared to the same periods 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 deficit accumulated during the development stage through August 31, 2009 is \$45,067,782, and we expect to continue to incur substantial losses in future periods if additional financing is obtained. We expect that if we obtain additional financing then 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 obtaining 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. Even if we obtain additional financing, 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 if we obtain additional financing to restart operations, 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 a discount to the current market price.

On September 18, 2003, we raised \$12,657,599 through the sale of 7,445,646 shares of our common stock at \$1.70 per share, with warrants to purchase an additional 3,164,395 shares of our common stock, at an exercise price of \$2.40 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 2,593,788 shares of our common stock at \$1.95 per share, with warrants to purchase an additional 920,121 shares of our common stock, at an exercise price of \$2.25 per share. All of these warrants expire 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 2,595,132 shares of our common stock at \$2.25 per share, with warrants to purchase an additional 648,784 shares of our common stock, at an exercise price of \$2.99 per share. We also issued warrants to purchase 227,074 shares of our common stock, at an exercise price of \$2.99 per share, to the placement agent. All of these warrants expire 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 351,598 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 6,071,013 shares of our common stock at \$2.50 per share, with warrants to purchase an additional 1,517,753 shares of our common stock, at an exercise price of \$3.85 per share. We also issued warrants to purchase 531,214 shares of our common stock, at an exercise price of \$3.85 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 133,500 warrants and 6,000 options which resulted in \$315,574 in cash proceeds.

To the extent any further warrants are exercised, we intend to use the proceeds for general working capital and corporate purposes. Currently, however, the exercise price of all of our outstanding warrants as disclosed above are significantly in excess of what our stock has been trading in calendar year 2009 as of the date of this Report.

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

Our operating cash outflows for the three months ended August 31, 2009 and 2008 have resulted primarily from research and development expenditures associated for PRTX-100 and administrative purposes. If additional financing is obtained, we expect to continue to use cash resources to fund operating losses and expect to continue to incur operating losses in fiscal 2010 and beyond due to continuing research and development activities if our operations are restarted.

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

We expect to continue to require investments in information technology and laboratory equipment to support our research and development activities. In August 2008, we sold laboratory equipment with net proceeds of \$200,000.

### **Net Cash Provided by Financing Activities and Financing Requirements Outlook**

We had no net cash inflows provided by financing activities for the three months ended August 31, 2009 and 2008, respectively.

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. If we obtain additional financing, we expect to continue to use our new cash and investments resources to fund operating and investing activities.

As of August 31, 2009, we had cash and cash equivalents of \$1,866,272 and net working capital of \$818,285. We have suffered recurring losses from operations and negative cash flows from operating activities. If we had continued operations beyond the end of third calendar quarter, without additional funds from third party sources, we would not have been able to meet our financial obligations. Additional financing or potential sublicensing of PRTX-100 will be required in order to fund and restart our operations. As a result, our independent registered public accounting firm, Grant Thornton LLP, indicated in their report on our 2009 financial statements that there is substantial doubt about our ability to continue as a going concern.

#### **Off Balance Sheet Arrangements and Contractual Obligations**

We have entered into the following contractual obligations:

- *Employee Agreements-Officers.* As previously disclosed in our Form 10-K filed on August 28, 2009, Messers. Kane and Rose voluntarily terminated their employment. Messers. Kane and Rose remain the CEO and CFO, respectively, of the Company. As of the date of this Report, while Mr. Rose has not accepted full time employment elsewhere, Mr. Kane is now currently also the Chairman and CEO of Patient Safety Technologies, Inc.
- *Directors Agreements.* To attract and retain qualified candidates to serve on the board of directors, we have previously entered into agreements with G. Kirk Raab, Chairman of the Board, Carleton A. Holstrom, Chairman of the Audit Committee, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro under which Messrs. Raab, Holstrom, Dr. Bauer, Mr. Tombros, Mr. Dougherty and Mr. Stagnaro received aggregate annual cash payments aggregating \$150,000, \$20,000, \$20,000, \$20,000, \$20,000 and \$20,000 respectively, as directors' fees. Pursuant to a Cash Waiver & Option Termination Agreement dated April 10, 2009, each of the outside Directors of the Company, G. Kirk Raab, Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro who were entitled to a Director's cash fee agreed to waive all such accrued and unpaid Director cash fees and terminate any rights for further cash fees. For Mr. Raab, those cash fees ceased as of April 1, 2009. For the other Directors, those cash fees ceased as of February 1, 2009. In addition, each of these Directors agreed to terminate immediately all of their existing stock options in the Company (vested and unvested).
- *Operating Lease – Office Space.* We entered into a three-year operating lease in New Hope, PA for 3,795 square feet of office and laboratory space. The lease commenced on January 9, 2004, and was originally to expire on February 28, 2007. On November 18, 2005, we modified the existing lease which added an additional 2,147 square feet and extended the lease term to January 31, 2008 and on April 30, 2007, we modified the existing lease and extended the lease term to January 31, 2010.
- *Operating Lease – Copier.* We entered into a sixty-three month operating lease for a multi-function copier. The lease commenced on December 16, 2004 and will expire on March 16, 2010.

#### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Intentionally Omitted.

#### **ITEM 4T. CONTROLS AND PROCEDURES**

##### *Evaluation of Disclosure Controls and Procedures*

Management of our company is responsible for establishing and maintaining effective disclosure controls and procedures as defined under Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934. As of August 31, 2009, an evaluation was performed, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that as of August 31, 2009, our disclosure controls and procedures were effective at the reasonable assurance level to ensure that information required to be disclosed by the Company in reports filed under the Exchange Act was recorded, processed, summarized and reported within the time period required by the Securities and Exchange Commission's rules and forms and accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

##### *Changes in Internal Control Over Financial Reporting*

During the quarter ended August 31, 2009 and thereafter, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### ITEM 1. LEGAL PROCEEDINGS

Not applicable.

### ITEM 1A. RISK FACTORS

Intentionally omitted.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable.

### ITEM 6. EXHIBITS

#### EXHIBIT INDEX

2.1	Stock Purchase Agreement among the Company, Don Hanosh and Enerdyne Corporation, dated December 1999	Incorporated by reference, to Exhibit 2.1 to the Company's 10-SB filing on December 6, 1999
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10.2	Board appointment executed by G. Kirk Raab	Incorporated by reference, to Exhibit 10.4 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
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10.7	Stock Redemption Agreement dated August 15, 2003, by and between the Company, Paul L. Mann, Leslie A. McCament-Mann, Gail Stewe and Elizabeth Sarah Anne Wiley	Incorporated by reference, to Exhibit 10.10 to the Company's Annual Report on Form 10-KSB/A filed on September 24, 2003.
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10.11	Description of the verbal agreement between the Company and Eugene A. Bauer, M.D.	Incorporated by reference to the Company's Current Report on Form 8-K filed on February 22, 2005.
10.12	Protalex, Inc. 2003 Stock Option Plan Amended and Restated as of July 29, 2005	Incorporated by reference to Appendix B to the Company's Proxy Statement filed on September 23, 2005.

10.13	Description of the verbal agreement between the Company and Peter G. Tombros	Incorporated by reference to the Company's Current Report on Form 8-K filed on November 14, 2005.
10.14	Modified lease agreement with Union Square LP, dated November 18, 2005	Incorporated by reference to Exhibit 99.1 to the Company's Current Report Form 8-K filed on November 22, 2005.
10.15	Employment offer letter executed by Marc L. Rose, CPA, Vice President, Chief Financial Officer, Treasurer and Corporate Secretary	Incorporated by reference, to Exhibit 10.2 to the Company's Quarterly Report on Form 10-QSB filed on January 14, 2005.
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10.20	Cash Waiver & Option Termination Agreement dated April 10, 2009 with G. Kirk Raab, Carleton A. Holstrom, Eugene A. Bauer, MD, Peter G. Tombros, Frank M. Dougherty and Thomas P. Stagnaro	Incorporated by reference to Exhibit 10.20 to the Company's Current Report Form 10-K filed on August 28, 2009.
10.21	Indemnification Agreement with Directors and Executive Officers dated August 28, 2009	Incorporated by reference to Exhibit 10.21 to the Company's Current Report Form 10-K filed on August 28, 2009.
31.1	Certification of Chief Executive Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Section 302(a) of the Sarbanes-Oxley Act	Filed herewith
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act	Filed herewith

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

## SIGNATURES

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

Date: October 15, 2009

PROTALEX, INC.

By: /s/ Steven H. Kane

Steven H. Kane, President and Chief  
Executive Officer

Date: October 15, 2009

By: /s/ Marc L. Rose

Marc L. Rose, Vice President of Finance,  
Chief Financial Officer, Treasurer  
and Corporate Secretary

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



**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

I, Steven H. Kane, 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 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 is made known to us by others, 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 quarterly report any change in the registrants' internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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 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 registrant's board of directors:
  - 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.

Dated: October 15, 2009

By: /s/ Steven H. Kane

Steven H. Kane  
President, Chief Executive Officer and Director

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**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

I, Marc L. Rose, 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 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 is made known to us by others, 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 quarterly report any change in the registrants' internal control over financial reporting that occurred during the registrant's most recent fiscal quarter 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 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 registrant's board of directors:
  - 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.

Dated: October 15, 2009

By: /s/ Marc L. Rose

Marc L. Rose  
Vice President of Finance, Chief Financial Officer, Treasurer and  
Corporate Secretary

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**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**

I, Steven H. Kane, Chief Executive Officer of Protalex, Inc. (the "Registrant"), do hereby certify pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code that:

(1) the Registrant's Quarterly Report on Form 10-Q for the quarter ended August 31, 2009 (the "Report"), to which this statement is filed as an exhibit, 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 results of operations of the Registrant.

Dated: October 15, 2009

By: /s/ Steven H. Kane

Steven H. Kane  
President, Chief Executive Officer and Director

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being "filed" as part of the Form 10-Q or as a separate disclosure document for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent that this Exhibit 32.1 is expressly and specifically incorporated by reference in any such filing.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

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**CERTIFICATION OF CHIEF FINANCIAL OFFICER**

I, Marc L. Rose, Chief Financial Officer of Protalex, Inc. (the "Registrant"), do hereby certify pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code that:

(1) the Registrant's Quarterly Report on Form 10-Q for the quarter ended August 31, 2009 (the "Report"), to which this statement is filed as an exhibit, 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 results of operations of the Registrant.

Dated: October 15, 2009

By: /s/ Marc L. Rose

Marc L. Rose  
Vice President of Finance, Chief Financial Officer, Treasurer and  
Corporate Secretary

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being "filed" as part of the Form 10-Q or as a separate disclosure document for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section. This certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent that this Exhibit 32.2 is expressly and specifically incorporated by reference in any such filing.

A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the Securities and Exchange Commission or its staff upon request.

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