Protalix BioTherapeutics, Inc.
Form 10-Q
November 09, 2009

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2009

OR

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

For the transition period from _____ to _____

001-33357
(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Florida	**65-0643773**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2 Snunit Street Science Park POB 455 Carmiel, Israel	**20100**
(Address of principal executive offices)	**(Zip Code)**

972-4-988-9488
(Registrant s telephone number, including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common stock, par value $0.001 per share	**NYSE Amex**

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 þ No o
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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o No o

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

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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

On November 1, 2009, approximately 77,265,801 shares of the Registrant s common stock, $0.001 par value, were outstanding.

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Except where the context otherwise requires, the terms, we, us, our or the Company, refer to the business of Protalix BioTherapeutics, Inc. and its consolidated subsidiaries, and Protalix or Protalix Ltd. refers to the business of Protalix Ltd., our wholly-owned subsidiary and sole operating unit.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth under the captions Business, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Risk Factors, and other statements included elsewhere in this Quarterly Report on Form 10-Q, which are not historical, constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding the expectations, beliefs, intentions or strategies for the future. When used in this report, the terms anticipate, believe, estimate, expect and intend and words or phrases of similar import, as they relate to ou our subsidiary or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

Examples of the risks and uncertainties include, but are not limited to, the following:

- the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;
- delays in our preparation and filing of applications for regulatory approval;
- delays in the approval or the potential rejection of any applications we file with the U.S. Food and Drug Administration, or the FDA, or other regulatory authorities;
- any lack of progress of our research and development (including the results of clinical trials we are conducting);
- obtaining on a timely basis sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies;
- our ability to obtain additional financing required to fund our research programs;
- the risk that we will not be able to develop a successful sales and marketing organization in a timely manner, if at all;
- our ability to establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationships with collaborators, distributors and partners;
- potential product liability risks and risks of securing adequate levels of product liability and clinical trial insurance coverage;
- the availability of reimbursement to patients from health care payors for any of our product candidates, if approved;
- the possibility of infringing a third party s patents or other intellectual property rights;

the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third parties;

the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites; and

other risks and uncertainties detailed in Section 1A of this Quarterly Report.

In addition, companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated by clinical trials of drug products, the FDA may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. These and other risks and uncertainties are detailed in Section 1A of our Annual Report on Form 10-K for the year ended December 31, 2008, and described from time to time in our future reports to be filed with the Securities and

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Exchange Commission. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

ProCellEx™ and UPLYSO™ are our trademarks. Each of the other trademarks, trade names or service marks appearing in this Quarterly Report belongs to its respective holder.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	September 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 22,610	$ 42,596
Accounts receivable	2,684	793
Total current assets	25,294	43,389
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	714	581
PROPERTY AND EQUIPMENT, NET	12,112	6,841
Total assets	$ 38,120	$ 50,811
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 1,891	$ 2,235
Other	5,009	3,292
Total current liabilities	6,900	5,527
LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT	1,143	937
Total liabilities	8,043	6,464
SHAREHOLDERS EQUITY	30,077	44,347
Total liabilities and shareholders equity	$ 38,120	$ 50,811

The accompanying notes are an integral part of the condensed consolidated financial statements.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except share data)
(Unaudited)

	Nine months ended		Three months Ended		Period from December 27, 1993* through
	September 30, 2009	September 30, 2008	September 30, 2009	September 30, 2008	September 30, 2009
REVENUES					$ 830
COST OF REVENUES					206
GROSS PROFIT					624
RESEARCH AND DEVELOPMENT EXPENSES (1)	$ 17,330	$ 15,817	$ 6,034	$ 6,133	71,747
less grants	(4,223)	(3,244)	(1,423)	(729)	(15,124)
	13,107	12,573	4,611	5,404	56,623
GENERAL AND ADMINISTRATIVE EXPENSES (2)	3,847	5,306	1,435	1,314	40,207
OPERATING LOSS	16,954	17,879	6,046	6,718	96,206
FINANCIAL INCOME NET	(450)	(2,041)	(152)	(222)	(4,655)
NET LOSS BEFORE CHANGE IN ACCOUNTING PRINCIPLE	16, 504	15,838	5,894	6,496	91,551
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE					(37)
NET LOSS FOR THE PERIOD	$ 16,504	$ 15,838	$ 5,894	$ 6,496	$ 91,514
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED:	$ 0.22	$ 0.21	$ 0.08	$ 0.09	

WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:					
Basic and diluted	76,236,399	75,879,778	76,564,441	75,924,657	
(1) Includes share-based compensation	1,026	965	363	293	7,636
(2) Includes share-based compensation	976	1,680	475	185	23,821

* Incorporation date. See Note 1a.

The accompanying notes are an integral part of the condensed consolidated financial statements.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY
(U.S. dollars in thousands, except share data)

	Common Stock (2)	Convertible Preferred Shares	Common Stock	Convertible Preferred Shares	Warrants	Additional paid-in capital	Deficit accumulated during development stage	Total
	Number of shares					Amount		
Balance at December 27, 1993(1)								
Changes during the period from December 27, 1993* through December 31, 2008:								
Common Stock and convertible preferred A, B and C shares and warrants issued for cash (net of issuance costs of $5,078)	38,856,127	398,227	$ 39	$ 1	$ 1,382	$ 73,836		$ 75,258
Exercise of options granted to employees and non-employees (includes Net Exercise)	2,948,420	847	3			413		416
Conversion of convertible preferred shares into common stock	24,375,870	(399,074)	24	(1)		(23)		
Change in accounting principle						(37)	$ 37	
Expiration of warrants					(34)	34		
Merger with a wholly owned subsidiary of the Company (net of issuance cost of $642)	583,280		1			240		241
Exercise of warrants	9,171,695		9		(1,348)	15,342		14,003
Restricted common stock issued for future services	2,667		*			8		8
						29,468		29,468

Share-based compensation					
Net loss for the period				(75,047)	(75,047)
Balance at December 31, 2008	**75,938,059**	**76**	**119,281**	**(75,010)**	**44,347**
Changes during the nine month period ended September 30, 2009 (Unaudited):					
Share-based compensation			2,002		2,002
Exercise of options granted to employees (includes Net Exercise)	745,004	1	231		232
Net loss for the period				(16,504)	(16,504)
Balance at September 30, 2009 (Unaudited)	**76,683,063**	**$ 77**	**$ 121,514**	**$ (91,514)**	**$ 30,077**

* Represents an amount less than $1.

(1) Incorporation date. See Note 1a.

(2) Common Stock, $0.001 par value; Authorized as of December 31, 2008 and September 30, 2009 - 150,000,000 shares.

The accompanying notes are an integral part of the condensed consolidated financial statements.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)
(Unaudited)

	Nine months ended		Period from December 27, 1993* through
	September 30, 2009	September 30, 2008	September 30, 2009
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss for the period	$ (16,504)	$ (15,838)	$ (91,514)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Cumulative effect of change in accounting principle			(37)
Share based compensation	2,002	2,645	31,457
Financial income, net (mainly exchange differences)	(164)	(823)	(1,240)
Depreciation and impairment of fixed assets	1,407	927	4,647
Changes in accrued liability for employee rights upon retirement	195	304	1,132
Gain on amounts funded in respect of employee rights upon retirement	(59)	(70)	(124)
Loss (Gain) on sale of fixed assets	10		4
Changes in operating assets and liabilities:			
Increase in accounts receivable	(1,724)	(1,243)	(2,233)
Increase in accounts payable and accruals	171	322	4,553
Net cash used in operating activities	$ (14,666)	$ (13,776)	$ (53,355)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	$ (5,648)	$ (2,643)	$ (14,841)
Investment grant received in respect of fixed assets			38
Investment in restricted cash deposit		(175)	(222)
Proceeds from sale of property and equipment	75		87
Amounts funded in respect of employee rights upon retirement	(60)	(123)	(576)
Net cash used in investing activities	$ (5,633)	$ (2,941)	$ (15,514)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Loan and convertible bridge loan received			$ 2,145
Repayment of loan			(1,000)
Issuance of shares and warrants, net of issuance cost		(56)	74,059
Exercise of options and warrants	$ 200	$ 3	14,619
			237

Merger with a wholly owned subsidiary of the Company, net of issuance cost			
Net cash provided by (used in) financing activities	$ 200	$ (53)	$ 90,060
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ 113	$ 1,002	$ 1,419
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(19,986)	(15,768)	22,610
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	42,596	61,813	
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 22,610	$ 46,045	$ 22,610

The accompanying notes are an integral part of the condensed consolidated financial statements.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)
(Unaudited)

(Continued) 2

	Nine months ended		Period from December 27, 1993* through
	September 30, 2009	September 30, 2008	September 30, 2009
SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION:			
Cash paid during the period for interest			$ 80
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Conversion of convertible bridge loan into shares			$ 1,145
Purchase of property and equipment	$ 2,047	$ 956	$ 2,047
Issuance cost not yet paid and accruals other	$ 5	$ 5	$ 5
Issuance cost paid by a grant of options			$ 21
Consultants and director credit balance converted into shares			$ 80
Exercise of options granted to employees	$ 32	$ 386	$ 32

* Incorporation date. See Note 1a.

The accompanying notes are an integral part of the condensed consolidated financial statements.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data)
(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES

a. General

1. Operation

Protalix BioTherapeutics, Inc. (the Company), and Protalix Ltd. (Protalix Ltd.), the Company s wholly-owned subsidiary which was incorporated in Israel on December 27, 1993, are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company s proprietary ProCellEx protein expression system (ProCellEx). In September 2009, the Company formed a subsidiary in connection with the EMEA application process in Europe. The new subsidiary, which is organized under the laws of the Netherlands, is a wholly-owned subsidiary of Protalix Ltd. The Company s lead product development candidate is prGCD (the proposed brand name for prGCD is UPLYSO) for the treatment of Gaucher disease, which the Company is developing using its ProCellEx protein expression system. Gaucher disease is a rare and serious lysosomal storage disorder in humans with severe and debilitating symptoms. In September 2009, the Company successfully completed its phase III pivotal study for UPLYSO. In December 2008, the Company initiated a clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with UPLYSO. The switchover-study is not a prerequisite for approval of UPLYSO.

In addition, in August 2009, the Company received Fast Track Designation for UPLYSO and in September 2009, the FDA s Office of Orphan Product Development granted UPLYSO Orphan Drug Status.

The Company has been in the development stage since its inception. Successful completion of development program and its transition to normal operations is dependent upon necessary regulatory approvals from the U.S. Food and Drug Administration (the FDA) prior to selling its products within the United States, and foreign regulatory approvals must be obtained to sell its products internationally. There can be no assurance that the Company will receive regulatory approval of any of its product candidates, and a substantial amount of time may pass before the Company achieves a level of sales adequate to support the Company s operations, if at all. The Company will also incur substantial expenditures in connection with the regulatory approval process and may need to raise additional capital during the developmental period. Obtaining marketing approval will be directly dependent on the Company s ability to implement the necessary regulatory steps required to obtain marketing approval in the United States and in other countries, and on the success of the Company s clinical trials. The Company cannot predict the outcome of these activities.

2. Liquidity and Financial Resources

The Company currently does not have sufficient resources to complete the commercialization of any of its proposed products. Based on its current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for approximately the next 15 months, although no assurance can be given that it will not need additional cash prior to such time. If there are unexpected increases in general and administrative expenses and research and development expenses, the Company may need to seek additional financing during the next 15 months.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data)
(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):

b. General Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with generally accepted accounting principles in the United States (GAAP) for interim financial information, Statement of Financial Accounting Standards (SFAS) No. 7, Accounting and Reporting by Development Stage Enterprises , and Article 10 of Regulation S-X under the Securities Exchange Act of 1934. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements.

In the opinion of management, all adjustments (of a normal recurring nature) considered necessary for a fair statement of the results for the interim periods presented have been included. Operating results for the interim period are not necessarily indicative of the results that may be expected for the full year.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Company s Annual Report on Form 10-K for the year ended December 31, 2008, filed with the Securities and Exchange Commission (the SEC). The comparative balance sheet at December 31, 2008 has been derived from the audited financial statements at that date, but does not include all of the information and notes required under GAAP for complete financial statements.

c. Net loss per share

Basic and diluted loss per share (LPS) are computed by dividing net loss by the weighted average number of shares of the Company s common stock, par value $.001 per share (the Common Stock), outstanding for each period.

Shares of restricted Common Stock and the shares of Common Stock underlying outstanding options of the Company were not included in the calculation of diluted LPS because the effect would be anti-dilutive.

Diluted LPS does not include options and restricted shares of Common Stock in the amount of 10,968,132 and 11,364,973 shares of Common Stock for the nine months ended September 30, 2008 and 2009, respectively, and 11,101,670 and 11,127,112 shares of Common Stock for the three months ended September 30, 2008 and 2009, respectively.

d. Newly issued and recently adopted Accounting Pronouncements

1. In April 2009, the Financial Accounting Standards Board (FASB) issued ASC Topic 825 Financial Instruments (formerly FSP No. FAS 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments. ASC 825 requires companies to disclose in interim financial statements the fair value of financial instruments within the scope of ASC Topic 820 Fair Value Measurements and Disclosures (formerly FASB Statement No. 107, Disclosures about Fair Value of Financial Instruments). However, companies are not required to provide in interim periods the disclosures about the concentration of credit risk of all financial instruments that are currently required in annual financial statements. The fair-value information disclosed in the footnotes must be presented together with the related carrying amount, making it clear whether the fair value and carrying amount represent assets or liabilities and how the carrying amount relates to what is reported in the balance sheet.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data)
(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):

ASC 825 also requires that companies disclose the method or methods and significant assumptions used to estimate the fair value of financial instruments and a discussion of changes, if any, in the method or methods and significant assumptions during the period. The ASC shall be applied prospectively and is effective for interim and annual periods ending after June 15, 2009. To the extent relevant, the Company adopted the disclosure requirements of this pronouncement for the quarter ended June 30, 2009, in conjunction with the adoption of ASC Topic 820 (formerly FSP FAS 157-4), ASC Topic 320 (formerly FSP FAS 115-2) and ASC Topic 958 (formerly FAS 124-2). The adoption of the new disclosure requirements did not have a material impact on the Company s financial statements.

2. In May 2009, the FASB issued ASC Topic 855 *Subsequent Events* (formerly SFAS No. 165, Subsequent Events). ASC 855 sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. ASC 855 will be effective for interim or annual periods ending after June 15, 2009 and will be applied prospectively. The Company adopted the provisions of ASC 855 for the quarter ended June 30, 2009. The adoption of ASC 855 did not have a material impact on the Company s condensed financial condition, results of operations or cash flows.

3. In June 2009, the FASB issued Accounting Standards Update (ASU) No. 2009-1, *Topic 105 Generally Accepted Accounting Principles* which amended ASC 105 The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (formerly SFAS No. 168 The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles A Replacement of FASB Statement No. 162). ASU 2009-1 establishes the FASB Accounting Standards Codification™ (Codification) as the single source of authoritative U.S. generally accepted accounting principles (U.S. GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. ASU 2009-1 and the Codification are effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification supersedes all existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. Following ASU 2009-1, the FASB will not issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts. Instead, the FASB will issue Accounting Standards Updates, which will serve only to: (a) update the Codification; (b) provide background information about the guidance; and (c) provide the bases for conclusions on the change(s) in the Codification. The adoption of ASU 2009-1 did not have a material impact on the Company s financial statements.

NOTE 2 STOCK TRANSACTIONS

a. During the nine months ended September 30, 2009, the Company issued 745,004 shares of Common Stock in connection with the exercise of a total of 828,615 options by certain officers and employees of the Company. The Company received aggregate cash proceeds equal to approximately $232 in connection with the exercise of 304,600 options and 524,015 of such options were exercised on a net-exercise basis.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(U.S. dollars in thousands, except share data)
(Unaudited)

NOTE 2 STOCK TRANSACTIONS (Continued):

b. On February 25, 2009, the Company s board of directors approved the grant of options to purchase 624,400 shares of Common Stock to its officers and employees with an exercise price equal to $2.65 per share. The options vest as follows:

(i) 504,000 of the options vest immediately upon the achievement of certain clinical and operational performance milestones, which milestones must be achieved within one year of the date of grant or the options will be forfeited. The Company recognized an expense for a portion of such based on management s assessment that it is probable that the milestones will be achieved during the 12-month period commencing on the date of grant. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $1,068, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 75.3%; risk-free interest rates of 2.95%; and expected life of 10 years.

(ii) 120,400 of the options vest as follows: 25% within one year from the date of grant, with the remainder vesting in 12 equal quarterly tranches over 36 months. The options are exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $212, based on the following weighted average assumptions: dividend yield of 0% for all years; expected volatility of 75.3%; risk-free interest rates of 1.84%; and expected life of six years. The Company s management assumed the simplified method to reflect the expected life regarding these options. The Company continued to use the simplified method in 2009 as the Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term due to the limited period of time its equity shares have been publicly traded.

NOTE 3 COMMITMENTS

The Company has entered into sub-contracting agreements with several clinical providers in Israel, the United States and certain other countries in connection with certain clinical services. As of September 30, 2009, total commitments under said agreements amounted to approximately $3,284.

NOTE 4 FAIR VALUE OF FINANCIAL INSTRUMENTS

The fair value of the financial instruments included in the Company s working capital is usually identical or close to their carrying value due to the short-term maturities of these instruments. The amounts funded in respect of employee rights are stated at surrender value which is close to their fair value.

NOTE 5 SUBSEQUENT EVENTS

The Company has performed an evaluation of subsequent events through November 9, 2009, which is the date the financial statements were issued.

During October and November 2009, the Company issued a total of 664,500 shares of Common Stock in connection with the exercise of options to purchase 689,404 shares of Common Stock by certain officers and employees of the Company. The Company received aggregate cash proceeds equal to approximately $58 in connection with the exercise of 180,282 options and 509,142 of such options were exercised on a net-exercise basis.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our condensed financial statements and the consolidated financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2008. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2008 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx™ protein expression system, or ProCellEx. Using our ProCellEx system, we are developing a pipeline of proprietary and biosimilar or generic versions of recombinant therapeutic proteins based on our plant cell-based expression technology that target large, established pharmaceutical markets and that rely upon known biological mechanisms of action. Our initial commercial focus has been on complex therapeutic proteins, including proteins for the treatment of genetic disorders, such as Gaucher disease and Fabry disease. We believe our ProCellEx protein expression system will enable us to develop proprietary recombinant proteins that are therapeutically equivalent or superior to existing recombinant proteins currently marketed for the same indications. Because we are primarily targeting biologically equivalent versions of highly active, well-tolerated and commercially successful therapeutic proteins, we believe our development process is associated with relatively less risk compared to other biopharmaceutical development processes for completely novel therapeutic proteins.

Our lead product development candidate is prGCD (taliglucerase) for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. On September 14, 2009, we announced that the proposed brand name for prGCD is UPLYSO. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. UPLYSO is our proprietary recombinant form of Glucocerebrosidase (GCD), an enzyme naturally found in human cells that is mutated or deficient in patients with Gaucher disease. In July 2007, we reached an agreement with the U.S. Food and Drug Administration, or the FDA, on the final design of our pivotal phase III clinical trial of prGCD, through the FDA s special protocol assessment (SPA) process. The phase III clinical trial was completed in September 2009 and, on October 15, 2009, we announced positive top-line results from the trial. We are currently submitting sections, on a serial basis, of a New Drug Application (NDA) for UPLYSO as part of a rolling submission allowed in connection with the Fast Track Designation granted to us by the FDA for UPLYSO and we anticipate such filing will be completed before the end of this year. In addition, we expect to submit similar applications with other comparable regulatory agencies in other countries shortly thereafter.

In addition to our recently completed phase III clinical trial, during the third quarter of 2008, we initiated a double-blind, follow-on extension study as part of the trial. We also initiated a home care treatment program for patients enrolled in the extension study and in December 2008, we initiated a clinical study evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with UPLYSO. The current standard of care for Gaucher patients is enzyme replacement therapy with Cerezyme™ which is produced by Genzyme Corporation and currently the only approved enzyme replacement therapy for Gaucher disease. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are injected into patients in whom the enzyme is lacking or dysfunctional. The switch-over study is not a prerequisite for approval of UPLYSO.

In July 2009, following a request by the FDA, we submitted a treatment protocol in order to address an expected shortage of the current enzyme replacement therapy approved for Gaucher disease. The treatment protocol was approved by the FDA in August 2009. In August 2009, we received Fast Track Designation for UPLYSO and in September 2009, the FDA s Office of Orphan Product Development granted UPLYSO Orphan Drug Status. The fast track mechanism was created to facilitate the development and approval of new drugs intended for the treatment of life-threatening conditions for which there are no effective treatments and which demonstrate the potential to

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address unmet medical needs for the conditions. The fast track process includes scheduling of meetings to seek FDA input into development plans, the option of submitting an NDA serially in sections rather than submitting all components simultaneously, the option to request evaluation of studies using surrogate endpoints, and the potential for a priority review. The fast track designation may be withdrawn by the FDA at any time. The fast track designation does not guarantee that we will qualify for or be able to take advantage of the expedited review procedures and does not increase the likelihood that UPLYSO will receive regulatory approval.

The Orphan Drug designation for UPLYSO for the treatment of Gaucher Disease provides special status to UPLYSO provided that it meets certain criteria. As a result of the orphan designation, we are qualified for the tax credit and marketing incentives of the Orphan Drug Act of 1983. A marketing application for a prescription drug product that has been designated as a drug for a rare disease or condition is not subject to a prescription drug user fee unless the application includes an indication for other than a rare disease or condition.

Although Gaucher disease is a relatively rare disease, it represents a large commercial market due to the severity of the symptoms and the chronic nature of the disease. The annual worldwide sales of Cerezyme were approximately $1.2 billion in 2008 according to public reports by Genzyme. UPLYSO is a plant cell expressed version of the GCD enzyme, developed through our ProCellEx protein expression system. UPLYSO has an amino acid, glycan and three-dimensional structure that is very similar to its naturally-produced counterpart as well as to Cerezyme, which is a mammalian cell expressed version of the same protein. We believe UPLYSO may prove more cost-effective than the currently marketed alternative due to the cost benefits of expression through our ProCellEx protein expression system. In addition, based on our laboratory testing, preclinical and clinical results, we believe that UPLYSO may have the potential for increased potency and efficacy compared to the existing enzyme replacement therapy for Gaucher disease, which may translate into lower dosages and/or less frequent treatments.

In addition to UPLYSO, we are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates, therapeutic protein candidates for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, an acetylcholinesterase enzyme-based therapy for biodefense and intoxication treatments and an additional undisclosed therapeutic protein, all of which are currently being evaluated in animal studies. During the quarter ended March 31, 2009, we held a pre IND (investigational new drug application) meeting with the FDA in connection with our acetylcholinesterase enzyme-based therapy for biodefense applications and are currently performing pre-clinical studies for this indication. We plan to file an investigational new drug application (IND) with the FDA with respect to this product candidate during 2009 or early 2010 and to initiate human clinical studies immediately thereafter. In September 2009, we announced preclinical data regarding pr-antiTNF, our proprietary product candidate for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing, spondylitis, psoriatic arthritis and plaque psoriasis. Our pr-antiTNF product candidate has an amino acid sequence that is similar to Enbrel , which is one of the treatments for patients of such diseases. We believe that we may be able to reduce the development risks and time to market for our product candidates as our product candidates are based on well-understood proteins with known biological mechanisms of actions. We hold the worldwide commercialization rights to our proprietary development candidates and we intend to establish an internal, commercial infrastructure and targeted sales force to market UPLYSO and our other products, if approved, in North America, the European Union and in other significant markets, including Israel. In addition we are continuously evaluating potential strategic marketing partnerships.

Since its inception in December 1993, Protalix Ltd. has generated significant losses in connection with its research and development, including the clinical development of UPLYSO. At September 30, 2009, we had an accumulated deficit of $91.5 million. Since we do not generate revenue from any of our product candidates, we expect to continue to generate losses in connection with the continued clinical development of UPLYSO and the research and development activities relating to our technology and other drug candidates. Such research and development activities may require further resources if we are to be successful. As a result, we believe that our operating losses are likely to be substantial over the next several years. We will need to enter into a collaboration and licensing arrangement or obtain additional funds for the commercialization of our lead product candidate, UPLYSO, and to further develop the research and clinical development of our other development programs.

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In September 2009, we formed a new subsidiary to facilitate the EMEA application process for marketing approval of UPLYSO in the European Union. The new subsidiary, which was organized under the laws of the Netherlands, is a wholly-owned subsidiary of Protalix Ltd.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing at the end of this Quarterly Report. We believe that the accounting policies below are critical for one to fully understand and evaluate our financial condition and results of operations.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Results of Operations

Three months ended September 30, 2009 compared to the three months ended September 30, 2008

Research and Development Expenses

Research and development expenses were $6.0 million for the three months ended September 30, 2009, a decrease of $99,000, or 1.6%, from $6.1 million for the three months ended September 30, 2008. The research and development expenses were partially offset by grants equal to $1.4 million from the Office of the Chief Scientist, or the OCS, during the three months ended September 30, 2009, an increase of approximately $694,000 compared to grants equal to $729,000 received from the OCS during the three months ended September 30, 2008.

We expect research and development expenses to remain consistent as the last quarter until UPLYSO is approved for marketing by the FDA, if at all, as we continue our ongoing advanced stage of clinical trials of UPLYSO, especially with respect to the submission of an NDA for UPLYSO for the treatment of Gaucher disease, the extension study that we initiated in the third quarter of 2008 for patients that have completed our phase III clinical trial and chose to continue the treatment, the switch over study we initiated in the fourth quarter of 2008 evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with UPLYSO and the treatment protocol.

General and Administrative Expenses

General and administrative expenses were $1.4 million for the three months ended September 30, 2009, an increase of $121,000, or approximately 9.3%, from $1.3 million for the three months ended September 30, 2008.

Financial Expenses and Income

Financial income was $152,000 for the three months ended September 30, 2009, a decrease of $70,000, or approximately 31.5%, from $222,000 for the three months ended September 30, 2008. The decrease resulted primarily from the devaluation of the U.S. dollar against the New Israeli Shekel, the NIS, and significantly lower interest rates available for deposits during the period.

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Nine months ended September 30, 2009 compared to the nine months ended September 30, 2008

Research and Development Expenses

Research and development expenses were $17.3 million for the nine months ended September 30, 2009, an increase of $1.5 million, or 9.5%, from $15.8 million for the nine months ended September 30, 2008. The increase resulted primarily from the increase of $1.3 million in costs related to consulting and subcontractors associated with research and development incurred by us in connection with our phase III clinical trial of UPLYSO. The increase was partially offset by grants of $4.2 million from the OCS, during the nine months ended September 30, 2009, an increase of approximately $979,000 compared to grants equal to $3.2 million received from the OCS during the nine months ended September 30, 2008.

We expect research and development expenses to remain consistent as the last quarter until UPLYSO is approved for marketing by the FDA, if at all, as we continue our ongoing advanced stage of clinical trials of UPLYSO, especially with respect to the submission of an NDA for UPLYSO for the treatment of Gaucher disease, the extension study that we initiated in the third quarter of 2008 for patients that have completed our phase III clinical trial and chose to continue the treatment, the switch over study we initiated in the fourth quarter of 2008 evaluating the safety and efficacy of switching Gaucher patients currently treated under the current standard of care to treatment with UPLYSO and the treatment protocol.

General and Administrative Expenses

General and administrative expenses were $3.8 million for the nine months ended September 30, 2009, a decrease of $1.5 million, or approximately 28.3%, from $5.3 million for the nine months ended September 30, 2008. The decrease resulted primarily from a decrease of approximately $704,000 in share based compensation due to certain stock options that were fully expensed during 2008 and, consequently, were not expensed in the nine months ended September 30, 2009.

Financial Expenses and Income

Financial income, net was $450,000 for the nine months ended September 30, 2009, a decrease of $1.6 million, or approximately 80.0%, from $2.0 million for the nine months ended September 30, 2008. The decrease resulted primarily from the devaluation of the U.S. dollar against the NIS and significantly lowers interest rates available for deposits during the period.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of any approved products to generate product sales revenue, we have not been profitable and have generated operating losses since our inception. To date, we have funded our operations primarily with proceeds equal to $31.3 million from the private sale of our shares of common stock and from sales of convertible preferred and ordinary shares of Protalix Ltd., and an additional $14.4 million in connection with the exercise of warrants issued in connection with the sale of such ordinary shares, through December 31, 2007. In addition, on October 25, 2007, we generated gross proceeds of $50 million in connection with an underwritten public offering of our common stock. We believe that the funds currently available to us as are sufficient to satisfy our capital needs for approximately the next 15 months.

Cash Flows

Net cash used in operations was $14.7 million for the nine months ended September 30, 2009. The net loss for the nine months ended September 30, 2009 of $16.5 million was partially offset by $2.0 million of non-cash share-based compensation and $1.4 million of depreciation expense. In addition, net loss was partially offset by an increase of $1.7 million due to an increase in accounts receivable. Net cash used in investing activities for the nine months ended September 30, 2009 was $5.6 million and consisted primarily of purchases of property and

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equipment. Net cash provided from financing activities for the nine months ended September 30, 2009 was approximately $200,000, consisting of exercise price paid in connection with certain exercise of stock options.

Net cash used in operations was $13.8 million for the nine months ended September 30, 2008. The net loss for the nine months ended September 30, 2008 of $15.8 million was partially offset by $2.6 million of non-cash share-based compensation. Net cash used in investing activities for the nine months ended September 30, 2008 was $2.9 million and consisted primarily of purchases of property and equipment. Net cash used in financing activities for the nine months ended September 30, 2008 was $53,000, consisting of expenses paid during such period in connection with the October 2007 underwritten offering.

Future Funding Requirements

We expect to incur losses from operations for the foreseeable future. We expect to continue incurring research and development expenses at similar levels to date until the approval of UPLYSO, if at all, including expenses related to the hiring of personnel and additional clinical trials. We expect that general and administrative expenses will increase slightly as we establish the initial infrastructure necessary in connection with the potential launch of UPLYSO in certain territories. In addition, we are upgrading our manufacturing facility that would meet the FDA requirements and the expected market demand for the manufacture of our product candidates, which will increase our capital expenditures.

We believe that our existing cash and cash equivalents and short-term investments will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for approximately the next 15 months. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates and the markets in which we intend to operate, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many factors, including the progress and results of our clinical trials, the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including certain pre marketing activities, product marketing, sales and distribution.

We will need to finance our future cash needs through corporate collaboration and licensing arrangements, public or private equity offerings or debt financings. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development or our pre marketing efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. The sale of additional equity or debt securities will likely result in dilution to our shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Effects of Inflation and Currency Fluctuations

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2009 or the nine months ended September 30, 2008.

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Currency fluctuations could affect us by increased or decreased costs mainly for goods and services acquired outside of Israel. We do not believe currency fluctuations have had a material effect on our results of operations during the nine months ended September 30, 2009 or the nine months ended September 30, 2008.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2009 and September 30, 2008.

Recently Issued Accounting Pronouncements

In April 2009, the FASB issued ASC Topic 825 Financial Instruments (formerly FSP No. FAS 107-1 and APB 28-1, Interim Disclosures about Fair Value of Financial Instruments, or ASC 825. ASC 825 requires companies to disclose in interim financial statements the fair value of financial instruments within the scope of ASC Topic 820 Fair Value Measurements and Disclosures (formerly FASB Statement No. 107, Disclosures about Fair Value of Financial Instruments). However, companies are not required to provide in interim periods the disclosures about the concentration of credit risk of all financial instruments that are currently required in annual financial statements. The fair-value information disclosed in the footnotes must be presented together with the related carrying amount, making it clear whether the fair value and carrying amount represent assets or liabilities and how the carrying amount relates to what is reported in the balance sheet. ASC 825 also requires that companies disclose the method or methods and significant assumptions used to estimate the fair value of financial instruments and a discussion of changes, if any, in the method or methods and significant assumptions during the period. The ASC shall be applied prospectively and is effective for interim and annual periods ending after June 15, 2009. To the extent relevant, we adopted the disclosure requirements of this pronouncement for the quarter ended June 30, 2009, in conjunction with the adoption of ASC Topic 820 (formerly FSP FAS 157-4), ASC Topic 320 (formerly FSP FAS 115-2) and Topic 958 (formerly FAS 124-2). The adoption of the new disclosure requirements did not have a material impact on our financial statements.

In May 2009, the FASB issued ASC Topic 855 Subsequent Events (formerly SFAS No. 165, Subsequent Events), or ASC 855. ASC 855 sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. ASC 855 will be effective for interim or annual periods ending after June 15, 2009 and will be applied prospectively. We adopted the provisions of ASC 855 for the quarter ended June 30, 2009. The adoption of ASC 855 did not have a material impact on our condensed financial condition, results of operations or cash flows.

In June 2009, the FASB issued Accounting Standards Update, or ASU, No. 2009-1, Topic 105 Generally Accepted Accounting Principles , or ASU 2009-1, which amended ASC 105 The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles (formerly SFAS No. 168 The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles A Replacement of FASB Statement No. 162). ASU 2009-1 establishes the FASB Accounting Standards Codification™ (Codification) as the single source of authoritative U.S. generally accepted accounting principles recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative U.S. GAAP for SEC registrants. ASU 2009-1 and the Codification are effective for financial statements issued for interim and annual periods ending after September 15, 2009. The Codification supersedes all existing non-SEC accounting and reporting standards. All other nongrandfathered non-SEC accounting literature not included in the Codification will become nonauthoritative. Following ASU 2009-1, the FASB will not issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts. Instead, the FASB will issue Accounting Standards Updates, which will serve only to: (a) update the Codification; (b) provide background information about the guidance; and (c) provide the bases for conclusions on the change(s) in the Codification. The adoption of ASU 2009-1 did not have a material impact on our financial statements.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Currency Exchange Risk

The currency of the primary economic environment in which our operations are conducted is the dollar. We are currently in the development stage with no significant source of revenues; therefore we consider the currency of the primary economic environment to be the currency in which we expend cash. Approximately 50% of our expenses and capital expenditures are incurred in dollars, and a significant source of our financing has been provided in U.S. dollars. Since the dollar is the functional currency, monetary items maintained in currencies other than the dollar are remeasured using the rate of exchange in effect at the balance sheet dates and non-monetary items are remeasured at historical exchange rates. Revenue and expense items are remeasured at the average rate of exchange in effect during the period in which they occur. Foreign currency translation gains or losses are recognized in the statement of operations.

Approximately 35% of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A revaluation of 1% of the NIS will affect our income before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Nine months ended September 30,		Year ended December 31,
	2009	2008	2008
Average rate for period (%)	3.9885	3.5130	3.5878
Rate at period end (%)	3.7580	3.4210	3.8020

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS. These measures, however, may not adequately protect us from material adverse effects due to the impact of inflation in Israel.

Interest Rate Risk

Our exposure to market risk is confined to our cash and cash equivalents. We consider all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase, that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents. The primary objective of our investment activities is to preserve principal while maximizing the interest income we receive from our investments, without increasing risk. We invest any cash balances primarily in bank deposits and investment grade interest-bearing instruments. We are exposed to market risks resulting from changes in interest rates. We do not use derivative financial instruments to limit exposure to interest rate risk. Our interest gains may decline in the future as a result of changes in the financial markets.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The controls evaluation was conducted under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

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Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the SEC, and that material information relating to our company and our consolidated subsidiary is made known to management, including the Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system s objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in internal controls

There were no changes to our internal controls over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the period ended September 30, 2009 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

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PART II OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2008.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

There were no unregistered sales of equity securities during the nine months ended September 30, 2009, other than the issuance of 439,680 shares of common stock, in the aggregate, in connection with the exercise by certain of our officers and employees of outstanding stock options to purchase 482,034 shares of common stock granted under our 2006 Stock Incentive Plan. We received cash proceeds equal to approximately $14,000 in connection with the exercise of 116,078 options and 365,956 options were exercised on a net-exercise basis. The shares were issued pursuant to exemptions from registration under Section 4(2) of the Securities Act of 1933, or the Securities Act.

Use of Proceeds

The effective date of our first registration statement, filed on Form S-3 under the Securities Act, which was accompanied by a registration statement on Form S-3 filed pursuant to Rule 462(b) under the Securities Act (Nos. 333-144801 and 333-146919), relating to a public offering of our common stock, was September 26, 2007 and the offering date was October 25, 2007. The sole book-running manager of the offering was UBS Investment Bank, and CIBC World Markets (now Oppenheimer) served as the co-manager. We sold 10,000,000 shares of common stock at a price per share of $5.00 in the offering. Our aggregate net proceeds (after underwriting discounts and expenses) amounted to approximately $46.0 million. The offering closed on October 30, 2007.

The amount of the underwriting discount paid by us was $3.5 million and the expenses of the offering, not including the underwriting discount, were approximately $810,000.

Between October 30, 2007 and September 30, 2009, we have used approximately $37.3 million of the net proceeds to fund our operating activities, including activities related to the development of our clinical and preclinical product candidates and for working capital, capital expenditures and other general corporate purposes. During the quarter ended September 30, 2009, our research and development expenses comprised approximately 80% of our operating expenses. We have deposited the net proceeds of the offering in accordance with our investment policy in short-term bank-deposits. There has been no material change in our planned use of proceeds from our public offering as described in our registration statement.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matters to a Vote of Security Holders

None.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit Number	Exhibit Description	Method of Filing
3.1	Amended and Restated Articles of Incorporation of the Company	Incorporated by reference to the Company s Registration Statement on Form S-4 filed on March 26, 1998
3.2	Article of Amendment to Articles of Incorporation dated June 9, 2006	Incorporated by reference to the Company s Registration Statement on Form 8-A filed on March 9, 2007
3.3	Article of Amendment to Articles of Incorporation dated December 13, 2006	Incorporated by reference to the Company s Registration Statement on Form 8-A filed on March 9, 2007
3.4	Article of Amendment to Articles of Incorporation dated December 26, 2006	Incorporated by reference to the Company s Registration Statement on Form 8-A filed on March 9, 2007
3.5	Article of Amendment to Articles of Incorporation dated February 26, 2007	Incorporated by reference to the Company s Registration Statement on Form 8-A filed on March 9, 2007
3.6	Amended and Restated By-Laws	Incorporated by reference to the Company s Quarterly Report on Form 10-Q filed on August 8, 2008
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer	Filed herewith
32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer	Filed herewith

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SIGNATURES

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

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: November 9, 2009

By: /s/ David Aviezer
David Aviezer, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 9, 2009

By: /s/ Yossi Maimon
Yossi Maimon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)