Protalix BioTherapeutics, Inc.
Form 10-Q
November 10, 2008

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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, 2008

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	**American Stock Exchange**

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 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 Smaller reporting company o
(Do not check if a 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 o No þ

On November 1, 2008, approximately 75,930,235 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 potential rejection of any applications we file with the United States 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 drug products, 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 subsidiary, 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 clinical trials, even after obtaining promising earlier trial results. 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, 2007, and described from time to time in our future reports to be filed with the Securities and Exchange Commission. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

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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, except share data)

	September 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 46,045	$ 61,813
Accounts receivable	2,913	1,354
Total current assets	48,958	63,167
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	657	464
PROPERTY AND EQUIPMENT, NET	6,273	4,506
Total assets	$ 55,888	$ 68,137
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 2,067	$ 899
Other	2,332	2,863
Total current liabilities	4,399	3,762
LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT	994	690
Total liabilities	5,393	4,452
SHAREHOLDERS EQUITY	50,495	63,685
Total liabilities and shareholders equity	$ 55,888	$ 68,137

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 and per share data)
(Unaudited)

	Nine Months Ended September 30,		Three Months Ended September 30,		Period from December 27, 1993* through September 30, 2008
	2008	2007	2008	2007	
REVENUES					$ 830
COST OF REVENUES					206
GROSS PROFIT					624
RESEARCH AND DEVELOPMENT EXPENSES (1)	$ 15,817	$ 9,537	$ 6,133	$ 3,830	47,410
less grants	(3,244)	(1,466)	(729)	(385)	(9,431)
	12,573	8,071	5,404	3,445	37,979
GENERAL AND ADMINISTRATIVE EXPENSES (2)	5,306	10,476	1,314	1,986	26,008
OPERATING LOSS	17,879	18,547	6,718	5,431	63,363
FINANCIAL INCOME NET	(2,041)	(1,191)	(222)	(685)	(4,489)
OTHER INCOME		(6)			(6)
NET LOSS BEFORE CHANGE IN ACCOUNTING PRINCIPLE	15,838	17,350	6,496	4,746	58,868
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE					(37)
NET LOSS FOR THE PERIOD	$ 15,838	$ 17,350	$ 6,496	$ 4,746	$ 58,831
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED:	$ 0.21	$ 0.27	$ 0.09	$ 0.07	

WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:					
Basic and diluted	75,879,778	65,275,435	75,924,657	65,674,568	
(1) Includes share-based compensation	965	1,979	293	895	5,640
(2) Includes share-based compensation	1,680	8,219	185	1,218	13,786

* 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, 2007:								
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	2,780,467	847	3			408		411
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	8,000		*			11		11
Share-based compensation						16,791		16,791
Net loss for the period							(43,030)	(43,030)
Balance at December 31, 2007	**75,775,439**		**76**			**106,602**	**(42,993)**	**63,685**
Changes during the nine month period ended September 30, 2008 (Unaudited):								
Restricted common stock issued for future services						(3)		(3)
Share-based compensation						2,648		2,648
Exercise (includes Net Exercise) of options granted to employees	154,796		*			3		3
Net loss for the period							(15,838)	(15,838)
Balance at September 30, 2008 (Unaudited)	75,930,235		$ 76			$ 109,250	$ (58,831)	$ 50,495

(1) Incorporation date, see Note 1a.

(2) Common Stock, $0.001 par value; Authorized as of December 31, 2007 and September 30, 2008 - 150,000,000 shares.

* Represents an amount less than $1.

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 September 30,		Period from December 27, 1993* through September 30,
	2008	**2007**	**2008**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss for the period	$ (15,838)	$ (17,350)	$ (58,831)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Cumulative effect of change in accounting principle			(37)
Share based compensation	2,645	10,198	19,426
Financial income, net (principal differences relate to currency transaction gains/losses)	(823)	(417)	(1,629)
Depreciation and impairment of fixed assets	927	530	2,866
Changes in accrued liability for employee rights upon retirement	304	193	994
Gain on amounts funded in respect of employee rights upon retirement	(70)	(34)	(174)
Gain on sale of fixed assets		(6)	(6)
Changes in operating assets and liabilities:			
Increase in accounts receivable	(1,243)	(264)	(2,388)
Increase in accounts payable and accruals	322	153	3,329
Net cash used in operating activities	$ (13,776)	$ (6,997)	$ (36,450)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	$ (2,643)	$ (1,072)	$ (8,465)
Investment grant received in respect of fixed assets			38
Investment in restricted cash deposit	(175)		(222)
Proceeds from sale of property and equipment		10	11
Amounts funded in respect of employee rights upon retirement	(123)	(89)	(654)
Amounts paid in respect of employee rights upon retirement		14	171
Net cash used in investing activities	$ (2,941)	$ (1,137)	$ (9,121)
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	3	$ 12,913	14,417
Deferred issuance cost		(21)	
Merger with a wholly owned subsidiary of the Company, net of issuance cost		(104)	237
Net cash (used) provided by financing activities	$ (53)	$ 12,788	$ 89,858
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ 1,002	$ 408	$ 1,758
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(15,768)	5,062	46,045
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	61,813	15,378	
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 46,045	$ 20,440	$ 46,045

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 September 30,		Period from December 27, 1993* through September 30,
	2008	2007	2008
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	$ 717	$ 956	$ 717
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
Issuance cost not yet paid against deferred issuance cost		$ 386	

* 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 and per share data)
(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES

a. General

1. Operation

Protalix BioTherapeutics, Inc. and its wholly-owned subsidiary, Protalix Ltd. (collectively, the Company), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company s proprietary ProCellEx™ protein expression system (ProCellEx). The Company s lead product development candidate is prGCD for the treatment of Gaucher disease, which the Company is developing using its ProCellEx protein expression system. The Company is currently enrolling and treating patients in a phase III clinical trial of prGCD, and has initiated an extension study in connection with the trial for patients that have completed the trial and chose to continue the treatment.

The Company has been in the development stage since its inception. The Company s successful completion of its development program and its transition to normal operations is dependent upon the Company s receipt of necessary regulatory approvals from the United States Food and Drug Administration (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 s products will receive regulatory approvals, 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 it might 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 other countries and 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 24 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, capital expenditures and research and development expenses, the Company may need to seek additional financing during the next 24 months.

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

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

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued)

financial statements in the Annual Report on Form 10-K for the year ended December 31, 2007, filed by the Company with the Securities and Exchange Commission (the Commission). The comparative balance sheet at December 31, 2007 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 and warrants 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, restricted shares of Common Stock and warrants of the Company in the amount of 12,233,626 and 10,968,132 shares of Common Stock for the nine months ended September 30, 2007 and 2008, respectively, and 11,887,934 and 11,101,670 shares of Common Stock for the three months ended September 30, 2007 and 2008, respectively.

d. Newly issued Accounting Pronouncements

1. In December 2007, the Financial Accounting Standards Board (the FASB) issued SFAS No. 141 (revised 2007), Business Combinations (SFAS 141(R)). SFAS 141(R) changes the accounting for business combinations, including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer s income tax valuation allowance and income tax uncertainties. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Early application is prohibited. The Company will be required to adopt SFAS 141(R) on January 1, 2009.

2. In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51 (SFAS 160). SFAS 160 amends ARB 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Ownership interests in subsidiaries held by parties other than the parent company of the subsidiary are required to be presented in the consolidated statement of financial position within equity, but separate from the parent company s equity. SFAS 160 requires that changes in a parent company s ownership interest while the parent company retains its controlling financial interest in its subsidiary should be accounted for in a manner similar to the accounting treatment of equity transactions. When a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary should be initially measured at fair value, with any gain or loss recognized in earnings. SFAS 160 requires consolidated net income to be reported in amounts that include the amounts attributable to

both the parent company and the noncontrolling interest. It also requires disclosure, on the face of the consolidated income statement, of the amounts of consolidated net income attributable to both parent companies and the noncontrolling interests.

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

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued)

SFAS 160 is effective for fiscal years (including interim periods within those fiscal years) beginning on or after December 15, 2008. Earlier adoption is prohibited. SFAS 160 is required to be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirement which shall be applied retrospectively for all periods presented. The Company is required to adopt SFAS 160 as of January 1, 2009. The Company is currently assessing the impact that SFAS 160 may have on its results of operations and financial position.

3. In December 2007, the FASB ratified EITF Issue No. 07-01, Accounting for Collaborative Arrangements (EITF 07-01). EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-01 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-01 is effective for fiscal years beginning after December 15, 2008 (January 1, 2009, for the Company). Companies are required to apply EITF 07-01 using a modified version of retrospective transition for those arrangements in place at the effective date. In addition, companies are required to report the effects of the application of EITF 07-01 as a change in accounting principle through retrospective application to all prior periods presented for all arrangements existing as of the effective date, unless it is impracticable to apply the effects of the change retrospectively. The Company is currently assessing the impact that EITF 07-01 may have on its results of operations and financial position.

4. In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities (SFAS 161). SFAS 161 is intended to improve financial reporting regarding derivative instruments and hedging activities by requiring enhanced disclosure to enable investors to better understand the effects of such derivative instruments and hedging activities on a company s financial position, financial performance and cash flows. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged (January 1, 2009, for the Company). SFAS 161 also improves transparency regarding the location and amounts of derivative instruments in a company s financial statements; how derivative instruments and related hedged items are accounted for under Statement of Financial Accounting Standards No. 133 Accounting for Derivative Instruments and Hedging Activities ; and how derivative instruments and related hedged items affect a company s financial position, financial performance and cash flows. The Company is currently evaluating the effect SFAS 161 will have on its financial statement presentations.

5. In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles (SFAS 162). The statement is intended to improve financial reporting by identifying a consistent hierarchy for selecting accounting principles to be used in preparing financial statements that are presented in conformity with U.S. generally accepted accounting principles (GAAP). SFAS 162 will go into effect 60 days following the Commission s approval of the Public Company Accounting Oversight Board Auditing amendments to AU Section 411 The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles . The Company does not expect the adoption of SFAS 162 to have a material impact on its results of operations and financial position.

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PROTALIX BIOTHERAPEUTICS, INC.

(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share data)

(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued)

e. Reclassifications

Certain figures in respect of prior years have been reclassified to conform to the current year presentation.

NOTE 2 STOCK TRANSACTIONS

a. During the nine months ended September 30, 2008, the Company issued 154,796 shares of Common Stock in connection with the exercise of 189,460 options by certain officers and employees of the Company. The Company received cash proceeds equal to $3 in connection with such exercises as 167,440 of such options were exercised on a net-exercise basis.

b. On February 7, 2008, the Company s board of directors approved the grant of options to purchase 50,000 shares of Common Stock to a newly appointed member of the Company s board of directors, at an exercise price of $3.02 per share. The options vest over a four-year period and are exercisable for a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of the grant using the Black-Scholes option-pricing model to be approximately $109, based on the following assumptions: dividend yield of 0% for all years; expected volatility of 62.5%; risk-free interest rates of 2.9%; and expected life of 10 years.

c. On February 7, 2008, the Company s board of directors approved the grant of options to purchase 1,900,000 shares of Common Stock, in the aggregate, to certain officers and employees of the Company, at an exercise price of $5.00 per share. The options vest variably over periods of up to five years and are exercisable for a 10-year period commencing on the date of grant. The Company estimated the fair value of the options on the date of the grant using the Black-Scholes option-pricing model to be approximately $2,766, based on the following assumptions: dividend yield of 0% for all years; expected volatility of 62.5%; risk-free interest rates of 2.9%; and expected life of six years.

d. In February 2008, the Company amended the stock option agreements of certain executive officers. As amended, such stock option agreements provide for the full acceleration of the vesting period of unvested options held by such officers immediately upon a change of control. The Company concluded that the amendments do not result in a modification accounting charge against share-based compensation.

NOTE 3 COMMITMENTS

a. In January 2008, the Company entered into a lease agreement for the expansion of its current facility. The term of the lease is 7.5 years, commencing upon the date the newly-leased space is ready for occupancy by the Company, with three options for additional five-year periods, for a total of 15 additional years. The monthly rental payment is approximately $25 and is subject to increase based on certain improvements to be performed by the lessor.

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PROTALIX BIOTHERAPEUTICS, INC.

(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share data)

(Unaudited)

NOTE 3 COMMITMENTS (Continued)

b. During the nine months ended September 30, 2008, the Company entered into contracts with certain third parties in connection with certain clinical services. The aggregate fees payable by the Company during the life of the agreements are equal to approximately $1.64 million.

NOTE 4 FAIR VALUE

On January 1, 2008, the Company adopted the methods of fair value as described in SFAS No. 157 (SFAS 157), which defines fair value, establishes a framework for measuring fair value in accordance with GAAP and expands disclosure about fair value measurements to value its financial assets and liabilities. As defined in SFAS No. 157, fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, SFAS No. 157 establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The adoption of SFAS 157 did not have a material impact on the Company s results of operations and financial condition as the Company does not have any financial assets and liabilities measured at fair value on a recurring basis subject to the requirements of SFAS 157.

NOTE 5 SUBSEQUENT EVENTS

In October 2008 the Company granted an option to purchase 160,000 shares of Common Stock to an officer of the Company with an exercise price equal to $2.35 per share. The option vests over a four-year period and is exercisable over a 10-year period commencing on the date of grant. The Company estimated the fair value of the option on the date of the grant using the Black-Scholes option-pricing model to be approximately $148, based on the following assumptions: dividend yield of 0% for all years; expected volatility of 62.5%; risk-free interest rates of 3.58%; and expected life of six years.

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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, 2007. 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 this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2007 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^{tm} protein expression system. Using our ProCellEx system, we are developing a pipeline of proprietary 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, and on female infertility disorders. 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 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 for the treatment of Gaucher disease, which we are developing using our ProCellEx protein expression system. In July 2007, we reached an agreement with the United States 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. We initiated enrollment and treatment of patients in our phase III clinical trial of prGCD in the third quarter of 2007. During third quarter of 2008, we initiated a double-blind, follow-on extension study as part of our phase III clinical trial. prGCD 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. The current standard of care for Gaucher disease is enzyme replacement therapy. Enzyme replacement therapy is a medical treatment in which recombinant enzymes are injected into patients in whom the enzyme is lacking or dysfunctional. 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, which is used in enzyme replacement therapy produced by Genzyme Corporation and currently the only approved enzyme replacement therapy for Gaucher disease, were approximately $1.1 billion in 2007, and $933 million for the nine months ended September 30, 2008, according to public reports by Genzyme. prGCD is a plant cell expressed version of the GCD enzyme, developed through our ProCellEx protein expression system. prGCD 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 prGCD 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 prGCD 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 prGCD, we are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes therapeutic protein candidates for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, and for female infertility disorders. We are also developing an acetylcholinesterase enzyme-based therapy for biodefense and intoxication treatments. We plan to file an investigational new drug application (IND) with the FDA with respect to at least one additional product by the first half of 2009. 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

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to establish an internal, commercial infrastructure and targeted sales force to market prGCD 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.

Our business is conducted by our wholly-owned subsidiary, Protalix Ltd., which we acquired through a reverse merger transaction effective December 31, 2006. The merger transaction was treated as a recapitalization for accounting purposes and, as such, the results of operations discussed below are those of Protalix Ltd. Prior to the merger transaction, we had not conducted any operations for several years. Protalix Ltd. was originally incorporated in Israel in December 1993. Since its inception in December 1993, Protalix Ltd. has generated significant losses in connection with its research and development, including the clinical development of prGCD. At September 30, 2008, we had an accumulated deficit of $58.8 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 prGCD and the research and development activities relating to our technology and other drug candidates. Such research and development activities are budgeted to expand over time and will 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 obtain additional funds for the commercialization of our lead product, prGCD, and to further develop the research and clinical development of our other programs.

Critical Accounting Policies

Our significant accounting policies are described in Note 1 to our condensed consolidated financial statements appearing at the beginning of this Quarterly Report on Form 10-Q.

Results of Operations

Three months ended September 30, 2008 compared to the three months ended September 30, 2007

Research and Development Expenses

Research and development expenses were $6.1 million for the three months ended September 30, 2008, an increase of $2.3 million, or 60%, from $3.8 million for the three months ended September 30, 2007. The increase resulted primarily from the increase of $1.9 million in salaries for new and existing employees and related consulting, sub contractors and the costs of materials associated with research and development. The increase is mainly due to the costs we incurred in connection with our phase III clinical trial of prGCD, which we commenced during the third quarter of 2007. Research and development expenses were offset by grants of $729,000 from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, or the OCS, during the three months ended September 30, 2008, an increase of $344,000, or 89%, compared to grants equal to $385,000 received from the OCS during the three months ended September 30, 2007.

We expect research and development expenses to continue to increase as we enter into a more advanced stage of clinical trials for our product candidates, especially with respect to the anticipated continued progress in our phase III clinical trial of prGCD and with the extension study that we initiated in the third quarter of 2008 for patients that have completed the trial and chose to continue the treatment.

General and Administrative Expenses

General and administrative expenses were $1.3 million for the three months ended September 30, 2008, a decrease of $672,000, or 34%, from $2.0 million for the three months ended September 30, 2007. The decrease resulted primarily from a $1.0 million decrease in share-based compensation which was the result of the decrease in the fair value of the common stock underlying the portions of certain outstanding stock options granted to consultants that vested during the three-month period ended September 30, 2008.

Financial Expenses and Income

Financial income was $222,000 for the three months ended September 30, 2008, a decrease of $463,000, or 68%, from $685,000 for the three months ended September 30, 2007. The decrease resulted primarily from the

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devaluation of the Dollar against the New Israeli Shekel, or the NIS, in the three months ended September 30, 2007, compared to the devaluation of the NIS in the three months ended on September 30, 2008. The decrease was partially offset by the higher interest income earned during the three months ended September 30, 2008. The increase was a result of our higher cash balance during that period.

Nine months ended September 30, 2008 compared to the nine months ended September 30, 2007

Research and Development Expenses

Research and development expenses were $15.8 million for the nine months ended September 30, 2008, an increase of $6.3 million, or 66%, from $9.5 million for the nine months ended September 30, 2007. The increase resulted primarily from the increase of $5.1 million in salaries for new and existing employees, related consulting and the costs of materials associated with research and development. Research and development expenses were offset by grants of $3.2 million from the OCS, during the nine months ended September 30, 2008, an increase of $1.8 million, or 121%, compared to grants equal to $1.5 million received from the OCS during the nine months ended September 30, 2007.

We expect research and development expenses to continue to increase as we enter into a more advanced stage of clinical trials for our product candidates, especially with respect to our phase III clinical trial of prGCD and with the extension study that we initiated in the third quarter of 2008 for patients that have completed the trial and chose to continue the treatment.

General and Administrative Expenses

General and administrative expenses were $5.3 million for the nine months ended September 30, 2008, a decrease of $5.2 million, or 49%, from $10.5 million for the nine months ended September 30, 2007. The decrease resulted primarily from a $6.5 million decrease in share-based compensation resulting from the decrease in the fair value of the shares of common stock underlying the portions of certain outstanding stock options granted to consultants that vested during the nine-month period ended September 30, 2008.

Financial Expenses and Income

Financial income was $2.0 million for the nine months ended September 30, 2008, an increase of $850,000, or 71%, from $1.2 million for the nine months ended September 30, 2007. The increase resulted primarily from a higher balance of cash and cash equivalents as of September 30, 2008, which primarily resulted from the interest income earned on the proceeds generated from our underwritten public offering in October 2007 and from the devaluation of the Dollar against the NIS.

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 24 months.

Cash Flows

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

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$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.

Net cash used in operations was $7.0 million for the nine months ended September 30, 2007. The net loss for the nine months ended September 30, 2007 of $17.4 million was partially offset by $10.2 million of non-cash share-based compensation. Net cash used in investing activities for the nine months ended September 30, 2007 was $1.1 million and consisted primarily of purchases of property and equipment. Net cash provided by financing activities for the nine months ended September 30, 2007 was $12.8 million, consisting of the proceeds from the exercise of certain warrants.

Future Funding Requirements

We expect to incur losses from operations for the foreseeable future. We expect to incur increasing research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that general and administrative expenses will also increase as we expand our finance and administrative staff and add infrastructure to support the general growth of the Company. In addition, we are considering a new manufacturing facility for the manufacture of our product candidates, which would increase our capital expenditures significantly.

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 for the next 24 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, 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 product marketing, sales and distribution.

We will need to finance our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. 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 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, 2008 or the nine months ended September 30, 2007.

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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, 2008 or the nine months ended September 30, 2007.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2008 and September 30, 2007.

Recently Issued Accounting Pronouncements

In December 2007, the Financial Accounting Standards Board, or the FASB, issued Statement of Financial Accounting Standards No. 141 (revised 2007), Business Combinations , or SFAS 141(R). SFAS 141(R) changes the accounting for business combinations, including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer s income tax valuation allowance and income tax uncertainties. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Early application is prohibited. We will be required to adopt SFAS 141(R) on January 1, 2009.

In December 2007, the FASB issued Statement of Financial Accounting Standards No. 160, Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51, or SFAS 160. SFAS 160 amends ARB No. 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Ownership interests in subsidiaries held by parties other than the parent company of the subsidiary are required to be presented in the consolidated statement of financial position within equity, but separate from the parent company s equity. SFAS 160 requires that changes in a parent company s ownership interest while the parent company retains its controlling financial interest in its subsidiary should be accounted for in a manner similar to the accounting treatment of equity transactions. When a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary should be initially measured at fair value, with any gain or loss recognized in earnings. SFAS 160 requires consolidated net income to be reported in amounts that include the amounts attributable to both the parent company and the noncontrolling interest. It also requires disclosure, on the face of the consolidated income statement, of the amounts of consolidated net income attributable to both parent companies and the noncontrolling interests.

SFAS 160 is effective for fiscal years (including interim periods within those fiscal years) beginning on or after December 15, 2008. Earlier adoption is prohibited. Companies are required to apply SFAS 160 prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirement which shall be applied retrospectively for all periods presented. We are required to adopt SFAS 160 as of January 1, 2009. We are currently assessing the impact that SFAS 160 may have on our results of operations and financial position.

In December 2007, the FASB ratified EITF Issue No. 07-01, Accounting for Collaborative Arrangements , or EITF 07-01. EITF 07-01 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-01 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-01 is effective for fiscal years beginning after December 15, 2008 (January 1, 2009, for our company). Companies are required to apply EITF 07-01 using a modified version of retrospective transition for those arrangements in place at the effective date. In addition, companies are required to report the effects of the application of EITF 07-01 as a change in accounting principle through retrospective application to all prior periods presented for all arrangements existing as of the effective date, unless it is impracticable to apply the effects of the change retrospectively. We are currently assessing the impact that EITF 07-01 may have on our results of operations and financial position.

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In March 2008, the FASB issued Statement of Financial Accounting Standards No. 161 Disclosures about Derivative Instruments and Hedging Activities , or SFAS 161. SFAS 161 is intended to improve financial reporting regarding derivative instruments and hedging activities by requiring enhanced disclosure to enable investors to better understand the effects of such derivative instruments and hedging activities on a company s financial position, financial performance and cash flows. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early application encouraged (January 1, 2009, for our company). SFAS 161 also improves transparency regarding the location and amounts of derivative instruments in a company s financial statements; how derivative instruments and related hedged items are accounted for under SFAS No. 133 Accounting for Derivative Instruments and Hedging Activities and how derivative instruments and related hedged items affect a company s financial position, financial performance and cash flows. We are currently evaluating the effect SFAS No. 161 will have on our financial statement presentations.

In May 2008, the FASB issued Statement of Financial Accounting Standards No. 162, The Hierarchy of Generally Accepted Accounting Principles , or SFAS 162. SFAS 162 is intended to improve financial reporting by identifying a consistent hierarchy for selecting accounting principles to be used in preparing financial statements that are presented in conformity with U.S. generally accepted accounting principles (GAAP). SFAS 162 will go into effect 60 days following the approval of the Public Company Accounting Oversight Board Auditing amendments to AU Section 411 The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles by the Securities and Exchange Commission, or the Commission. We do not expect the adoption of SFAS 162 to have a material impact on our results of operations and financial position.

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 the 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,
	2008	2007	2007
Average rate for period	3.5130	4.1628	4.1081
Rate at period end	3.4210	4.0130	3.8460

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.

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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 Commission 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.

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 Commission, 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 change in 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, 2008 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

We describe our business risk factors below. This description includes any material changes to and supersedes the description of the risk factors associated with our business previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2007.

We currently have no product revenues and will need to raise additional capital to operate our business, which may not be available on favorable terms, or at all, and which will have a dilutive effect on our shareholders.

To date, we have generated no revenues from product sales and only minimal revenues from research and development services and other fees. Our accumulated deficit as of September 30, 2008 was $58.8 million. For the years ended December 31, 2007, 2006 and 2005, we had net losses of $22.5 million, $9.4 million and $5.7 million, respectively, primarily as a result of expenses incurred through a combination of research and development activities and expenses supporting those activities, which includes share-based compensation expense. Drug development and commercialization is very capital intensive. Until we receive approval from the FDA and other regulatory authorities for our drug candidates, we cannot sell our drugs and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of any equity or debt offerings, cash on hand, licensing fees and grants. Over the next 12 months, we expect to spend a minimum of approximately $12 million on preclinical and clinical development for our products under development. Based on our current plans and capital resources, we believe that our cash and cash equivalents will be sufficient to enable us to meet our minimum planned operating needs for approximately the next 24 months. However, changes may occur that could consume our existing capital at a faster rate than projected, including, among others, changes in the progress of our research and development efforts, the cost and timing of regulatory approvals and the costs of protecting our intellectual property rights. We may seek additional financing to implement and fund product development, preclinical studies and clinical trials for the drugs in our pipeline, as well as additional drug candidates and other research and development projects. If we are unable to secure additional financing in the future on acceptable terms, or at all, we may be unable to commence or complete planned preclinical and clinical trials or obtain approval of our drug candidates from the FDA and other regulatory authorities. In addition, we may be forced to reduce or discontinue product development or product licensing, reduce or forego sales and marketing efforts and other commercialization activities or forego attractive business opportunities in order to improve our liquidity and to enable us to continue operations which would have a material adverse effect on our business and results of operations. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our shareholders.

Clinical trials are very expensive, time-consuming and difficult to design and implement and may result in unforeseen costs which may have a material adverse effect on our business and results of operations.

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time-consuming. Our drug candidates are in early stages of preclinical studies or clinical trials. We estimate that we will be able to complete our current phase III clinical trial of prGCD and file an NDA by the end of the second half of 2009. Other clinical trials of prGCD, will conclude somewhat after, and any of our other potential drug candidates will take at least several years to complete. Preliminary and initial results from a clinical trial do not necessarily predict final results, and failure can occur at any stage of the trials. We may encounter problems that cause us to abandon or repeat preclinical studies or clinical trials. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier trials. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. Failure or delay in the commencement or completion of our clinical trials may be caused by several factors, including:

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unforeseen safety issues;

determination of dosing issues;

lack of effectiveness during clinical trials;

slower than expected rates of patient recruitment;

inability to monitor patients adequately during or after treatment;

inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and

lack of sufficient funding to finance the clinical trials.

Any failure or delay in commencement or completion of any clinical trials may have a material adverse effect on our business and results of operations. In addition, we or the FDA or other regulatory authorities may suspend our clinical trials at any time if it appears that we are exposing participants to unacceptable safety or health risks or if the FDA or such other regulatory authorities, as applicable, find deficiencies in our IND submissions or the conduct of these trials. Any suspensions of our clinical trials may have a material adverse effect on our business and results of operations.

Trading of our common stock is limited.

Our common stock began trading on the American Stock Exchange in March 2007. To date, the liquidity of our common stock is limited, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and changes in security analyst and media coverage, if at all. These factors may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and ask prices for our common stock.

In connection with the merger, substantially all of the former shareholders of Protalix Ltd. entered into lock-up agreements with respect to their shares of our common stock to satisfy Israeli tax laws and contractual obligations. The lock-up agreements prohibited such former shareholders of Protalix Ltd. from, directly or indirectly, selling or otherwise transferring the shares of our common stock issued to them in connection with the merger during a period commencing upon the closing of the merger and ending on January 1, 2009. However, during such period, each such former Protalix Ltd. shareholder was permitted, under the terms of the lock-up agreements and the tax ruling described below, to sell an aggregate of 10% of each such shareholder s original number of locked-up shares. All permitted sales of locked-up shares that may be made during such time period are cumulative. On June 11, 2008, after completing discussions with the Israeli tax authorities regarding the tax ruling, we approved the early termination of the lock-up agreements for holders of 5% or less of our outstanding shares as of the closing of the merger. The early termination of the lock-up agreements allows an additional 22,929,381 shares of our common stock to become eligible for sale on the public market. However, up to 35,875,319 shares of our common stock and options and warrants to purchase 3,046,052 shares of our common stock, remain subject to the lock-up agreements until January 1, 2009.

Under applicable Israeli tax law incorporated by reference into the tax ruling obtained by Protalix Ltd. from the Israeli tax authorities in connection with the merger, until January 1, 2009, we must maintain our holding of at least 51% of Protalix Ltd. and our shareholders at the time of the consummation of the merger must maintain, in the aggregate, holdings of at least 51% of our outstanding share capital. This restriction limits, to an extent, the volume of our shares available for public trading.

In the absence of an active public trading market, an investor may be unable to liquidate its investment in our common stock. Trading of a relatively small volume of our common stock may have a greater impact on the trading price of our stock than would be the case if our public float were larger. Further, the limited liquidity could be an indication that the trading price is not reflective of the actual fair market value of our common stock.

Future sales of our common stock could reduce our stock price.

Sales by shareholders of substantial amounts of our shares, the issuance of new shares by us or the perception that these sales may occur in the future, could affect materially and adversely the market price of our common stock. As described herein, substantially all of the former shareholders of Protalix Ltd. (holding at that time, in the aggregate, 65,094,232 shares of our common stock and options and warrants to purchase 3,628,826

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shares of our common stock) entered into lock-up agreements with respect to their securities of our company to satisfy Israeli tax laws and contractual obligations. The lock-up agreements prohibit such former shareholders of Protalix Ltd. from, directly or indirectly, selling or otherwise transferring the shares of our common stock issued to them in connection with the merger during a period commencing upon the closing of the merger and ending on January 1, 2009. However, during such period, each such former Protalix Ltd. shareholder may, under the terms of the lock-up agreements and a tax ruling received by Protalix Ltd. from the Israeli tax authorities in connection with the merger, sell an aggregate of 10% of each such shareholder s original number of locked-up shares. On June 11, 2008, after completing discussions with the Israeli tax authorities regarding the tax ruling, we approved the early termination of the lock-up agreements for holders of 5% or less of our outstanding shares as of the closing of the merger. The early termination of the lock-up agreements allows an additional 22,929,381 shares of our common stock to become eligible for sale on the public market.

In addition, on January 1, 2009, the remaining lock-up agreements entered into in connection with the merger will expire which will allow an additional 35,875,319 shares of our common stock and options and warrants to purchase 3,046,052 shares of our common stock to be available for sale on the public market, subject in most cases to the limitations of either Rule 144 or Rule 701 under the Securities Act.

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

Unregistered Sales of Equity Securities

There have been no unregistered sales of equity securities during the quarter ended September 30, 2008, other than the issuance of 154,796 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 189,460 shares of common stock granted under our 2006 Stock Incentive Plan. We received cash proceeds equal to $3 in connection with such exercises as 167,440 of such 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.

Use of Proceeds

The effective date of our first registration statement, filed on Form S-3 under the Securities Act of 1933, 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 & Co., Inc.) served as the co-manager. In the offering we sold 10,000,000 shares of common stock at a price per share of $5.00. Our aggregate net proceeds (after underwriting discounts and expenses) amounted to approximately $46 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.

To date, the net proceeds of the offering were invested in accordance with our investment policy in short-term deposits. We intend to use the proceeds in the manner set forth in our prospectus of October 25, 2007.

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, SEC File No. 333-48677
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, SEC File No. 001-33357
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, SEC File No. 001-33357
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, SEC File No. 001-33357
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, SEC File No. 001-33357
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, SEC File No. 001-33357
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 10, 2008

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

Date: November 10, 2008

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