

Protalix BioTherapeutics, Inc.

Form 10-Q/A

March 06, 2009

**Table of Contents**

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

**FORM 10-Q/A  
(Amendment No. 1)**

(Mark One)

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

For the quarterly period ended March 31, 2008

**OR**

**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  
Common stock, par value \$0.001 per share**

**Name of each exchange on which registered  
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  No   
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See 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  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(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  No

On May 1, 2008, approximately 75,883,046 shares of the Registrant's common stock, \$0.001 par value, were outstanding.

---

**FORM 10-Q/A**  
**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I FINANCIAL INFORMATION</u></b>	
<b><u>Cautionary Statement Regarding Forward-Looking Statements</u></b>	ii
<b><u>Item 1. Financial Statements</u></b>	
<u>Condensed Consolidated Balance Sheets As of March 31, 2008 (Unaudited) and December 31, 2007</u>	1
<u>Condensed Consolidated Statements of Operations (Unaudited) For the Three Months Ended March 31, 2008 and 2007; and for the Period from December 27, 1993 through March 31, 2008</u>	2
<u>Condensed Consolidated Statement of Changes in Shareholders Equity As of March 31, 2008 (Unaudited) and December 31, 2007</u>	3
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) For the Three Months Ended March 31, 2008 and 2007; and for the Period from December 27, 1993 through March 31, 2008</u>	4
<u>Notes to Condensed Consolidated Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	18
<u>Item 4. Controls and Procedures</u>	19
<b><u>PART II OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	21
<u>Item 1A. Risk Factors</u>	21
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	21
<u>Item 3. Defaults Upon Senior Securities</u>	21
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	21
<u>Item 5. Other Information</u>	22
<u>Item 6. Exhibits</u>	22
<u>Signatures</u>	24
<u>EX-31.1: CERTIFICATION</u>	
<u>EX-31.2: CERTIFICATION</u>	
<u>EX-32.1: CERTIFICATION</u>	
<u>EX-32.2: CERTIFICATION</u>	

**Table of Contents**

*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 Annual 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 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 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 them against third parties; and

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.

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.

**Table of Contents**

**EXPLANATORY NOTE**

The Company is restating its financial statements for the quarterly period ended March 31, 2007 by amending its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2008 to change the accounting treatment of certain stock-based compensation of non-employees required by SFAS 123(R), *Share-Based Payment*, or SFAS 123R, for certain transactions with nonemployees.

All amendments and restatements to the financial statements are non-cash in nature.

An explanation of the change in accounting treatment and its impact on the Company's financial statements is contained in Note 2 to the financial statements contained in Item 1 of this report.

The following sections of this Form 10-Q/A have been amended to reflect the restatement:

Part I Item 1 Financial Statements

Part I Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations

Other than as stated above, this Form 10-Q/A continues to speak as of March 31, 2008 or (where applicable) as of the date of the filing of the original Form 10-Q, and the information in this Form 10-Q/A does not modify or update any other item or disclosure in the original Form 10-Q or reflect any other events occurring after the filing of the original Form 10-Q.

This amended Form 10-Q/A should be read in conjunction with any periodic reports that have been filed subsequent to the date of the filing of the original Form 10-Q.

**Table of Contents****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)

	<b>March 31, 2008 (Unaudited)</b>	<b>December 31, 2007</b>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 57,782	\$ 61,813
Accounts receivable	2,096	1,354
Total current assets	59,878	63,167
<b>FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT</b>	544	464
<b>PROPERTY AND EQUIPMENT, NET</b>	5,404	4,506
Total assets	\$ 65,826	\$ 68,137
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accruals:		
Trade	\$ 1,057	\$ 899
Other	3,148	2,863
Total current liabilities	4,205	3,762
<b>LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT</b>	872	690
Total liabilities	5,077	4,452
<b>SHAREHOLDERS EQUITY</b>	60,749	63,685
Total liabilities and shareholders equity	\$ 65,826	\$ 68,137

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



Table of Contents

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

	Three Months Ended		Period from
	March 31,	March 31,	December 27,
	2008	2007	1993*
		(restated)	through
			March 31, 2008
			(restated)
REVENUES			\$ 830
COST OF REVENUES			206
<b>GROSS PROFIT</b>			<b>624</b>
RESEARCH AND DEVELOPMENT EXPENSES (1)	\$ 5,653	\$ 3,226	37,955
less grants	(1,366)	(738)	(7,553)
	4,287	2,488	30,402
GENERAL AND ADMINISTRATIVE EXPENSES (2)	1,976	6,392	31,572
OPERATING LOSS	6,263	8,880	61,350
FINANCIAL INCOME NET	(1,150)	(331)	(3,598)
OTHER INCOME			(6)
NET LOSS BEFORE CHANGE IN ACCOUNTING PRINCIPLE	5,113	8,549	57,746
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE			(37)
NET LOSS FOR THE PERIOD	\$ 5,113	\$ 8,549	\$ 57,709
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED:	\$ 0.07	\$ 0.13	
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER COMMON STOCK:			
Basic and diluted	75,811,866	64,365,376	

(1) Includes share-based compensation	1,327	900	6,711
(2) Includes share-based compensation	847	5,650	21,847

\* Incorporation  
date. See Note  
1a.

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

2

---

**Table of Contents**

**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) Number of shares	Convertible Preferred Shares	Convertible Common Stock	Convertible Preferred Shares	Warrants	Additional paid-in capital Amount	Deficit accumulated during development stage	Total
<b>Balance at December 27, 1993(1)</b>								
<b>Changes during the period from December 27, 1993 through December 31, 2007 (restated):</b>								
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
	9,171,695		9		(1,348)	15,342		14,003

Exercise of warrants					
Restricted common stock issued for future services	8,000	*	11		11
Share-based compensation			26,394		26,394
Net loss for the period				(52,633)	(52,633)
<b>Balance at December 31, 2007 (restated)</b>	<b>75,775,439</b>	<b>76</b>	<b>116,205</b>	<b>(52,596)</b>	<b>63,685</b>
<b>Changes during the three month period ended March 31, 2008 (Unaudited):</b>					
Restricted common stock issued for future services			(6)		(6)
Share-based compensation			2,180		2,180
Exercise (includes Net Exercise) of options granted to employees	92,459	*	3		3
Net loss for the period				(5,113)	(5,113)
<b>Balance at March 31, 2008 (Unaudited) (restated)</b>	<b>75,867,898</b>	<b>\$ 76</b>	<b>\$ 118,382</b>	<b>\$ (57,709)</b>	<b>\$ 60,749</b>

\* Represents an amount less than \$1.

(1) Incorporation date. See Note 1a.

(2) Common Stock, \$0.001 par value; Authorized as of December 31,

2007 and  
March 31, 2008  
- 150,000,000  
shares.

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

3

---

**Table of Contents**

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

	<b>Three Months Ended</b>		<b>Period from</b>
	<b>March</b>	<b>March 31,</b>	<b>December 27,</b>
	<b>31,</b>	<b>2007</b>	<b>1993*</b>
	<b>2008</b>	<b>(restated)</b>	<b>through</b>
			<b>March 31, 2008</b>
			<b>(restated)</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss for the period	\$ (5,113)	\$ (8,549)	\$ (57,709)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Cumulative effect of change in accounting principle			(37)
Share based compensation	2,174	6,550	28,558
Financial income net (principal differences relate to currency exchange rates)	(580)	(43)	(1,386)
Depreciation and impairment of fixed assets	262	132	2,201
Changes in accrued liability for employee rights upon retirement	182	74	872
Gain on amounts funded in respect of employee rights upon retirement	(41)	(5)	(145)
Gain on sale of fixed assets			(6)
Changes in operating assets and liabilities:			
Increase in accounts receivable	(658)	(886)	(1,803)
Increase (decrease) in accounts payable and accruals	(33)	(129)	2,974
Net cash used in operating activities	\$ (3,807)	\$ (2,856)	\$ (26,481)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchase of property and equipment	\$ (817)	\$ (516)	\$ (6,639)
Investment grant received in respect of fixed assets			38
Investment in restricted cash deposit			(47)
Proceeds from sale of property and equipment		4	11
Amounts funded in respect of employee rights upon retirement	(39)	(30)	(570)
Amounts paid in respect of employee rights upon retirement		8	171

Net cash used in investing activities	\$ (856)	\$ (534)	\$ (7,036)
---------------------------------------	----------	----------	------------

**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	\$ (20)		74,095
Exercise of options and warrants	\$ 3	\$ 12,910	14,417
Merger with a wholly-owned subsidiary of the Company, net of issuance cost		(39)	237
Net cash provided by financing activities	\$ (17)	\$ 12,871	\$ 89,894

**EFFECT OF EXCHANGE RATE**

<b>CHANGES ON CASH</b>	\$ 649	\$ 37	\$ 1,405
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	(4,031)	9,518	57,782
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	61,813	15,378	

<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	\$ 57,782	\$ 24,896	\$ 57,782
--	-----------	-----------	-----------

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

**Table of Contents**

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

(Continued) 2

	<b>Three Months Ended</b>		<b>Period from</b>
	<b>March</b>	<b>March 31,</b>	<b>December 27,</b>
	<b>31,</b>	<b>2007</b>	<b>1993*</b>
	<b>2008</b>	<b>(restated)</b>	<b>through</b>
			<b>March 31,</b>
			<b>2008</b>
			<b>(restated)</b>
<b>SUPPLEMENTARY DISCLOSURE OF CASH FLOW INFORMATION:</b>			
Cash paid during the period for interest			\$ 80
 <b>SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:</b>			
Conversion of convertible bridge loan into shares			\$ 1,145
Purchase of property and equipment	\$ 1,009	\$ 249	\$ 1,009
Issuance cost not yet paid and accruals other:	\$ 41	\$ 5	\$ 41
Issuance cost paid by a grant of options			\$ 21
Consultants and director credit balance converted into shares			\$ 80
Merger with a wholly owned subsidiary of the Company			
Issuance cost setoff against accounts payable		\$ 65	

\* Incorporation date. See Note 1a.

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



**Table of Contents**

**PROTALIX BIOTHERAPEUTICS, INC.**  
(a development stage company)  
**NOTES TO 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 its wholly-owned subsidiary, Protalix Ltd. (the Subsidiary or Protalix Ltd.), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company's proprietary ProCellEx<sup>®</sup> 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.

During the period from 2003 to 2005, Protalix Ltd. was a party to a research and development services contract with a pharmaceutical company pursuant to which the Company agreed to provide certain research and development services. The Company earned total revenues of \$830 throughout the duration of the contract in consideration for the performance of such services. The contract expired in the first quarter of 2005, and, since that time, the Company has not focused efforts on providing any further research and development services for third parties.

The Company has been in the development stage since its inception (see 2 below). 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. The Merger**

On December 31, 2006, the Company (formerly Orthodontix, Inc.) consummated the acquisition of Protalix Ltd., a privately-held Israeli biotechnology company incorporated on December 27, 1993, by the merger (the Merger) of its wholly owned subsidiary, Protalix Acquisition Co., Ltd., with Protalix Ltd. At and as of the Merger, the former shareholders of Protalix Ltd. received a number of shares of the Company's common stock, par value \$.001 per share (the Common Stock), equal to more than 99% of the outstanding shares of Common Stock. As a result, Protalix Ltd. is now the Company's wholly-owned subsidiary. As of that date, for accounting purposes, the Merger was accounted for as a recapitalization of Protalix Ltd. Accordingly, the historical financial statements of the Company reflect the historical operations and financial statements of Protalix Ltd. before the Merger.



**Table of Contents**

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

**NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):**

All share and per share data provided in these notes to the financial statements have been retroactively restated to reflect the conversion ratio related to the exchange of shares in the Merger (and giving effect to the one-for-ten reverse stock split), unless otherwise stated herein. 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 at least 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 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 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 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 13,008,658 and 10,565,151 shares of Common Stock for the three months ended March 31, 2007 and 2008, respectively.

**d. Newly issued and recently adopted Accounting Pronouncements**

1. In September 2006, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements ( SFAS 157 ). SFAS 157 defines fair value, establishes a framework, provides guidance regarding the methods to be used for measuring fair value and expands the required disclosure regarding fair value measurements.

**Table of Contents**

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

**NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):**

SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company adopted SFAS 157 on January 1, 2008. The adoption did not have any impact on the Company's results of operations and financial position since no other assets or liabilities are recognized or disclosed at fair value.

2. In February 2007, the FASB issued Statement of Financial Accounting Standards No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities" including an amendment of FASB Statement No. 115 (SFAS 159). SFAS 159 is expected to expand the use of fair value accounting but does not affect existing standards that require certain assets or liabilities to be carried at fair value. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company adopted SFAS 159 on January 1, 2008. The adoption did not have any impact on the Company's financial position since the Company did not elect the fair value option for any assets or liabilities under SFAS 159.
3. In December 2007, the FASB issued Statement of Financial Accounting Standards 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.
4. 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" (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 its parent company 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. 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.

**Table of Contents**

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

**NOTE 1 SIGNIFICANT ACCOUNTING POLICIES (Continued):**

5. 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.
  
6. In March 2008, the FASB issued Statement of Financial Accounting Standards 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.

**e. Reclassifications**

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

**NOTE 2 RESTATEMENT OF CONSOLIDATED FINANCIAL STATEMENTS**

The Company has restated its statements of operations, changes in shareholders' equity and cash flows for the year ended December 31, 2007, the quarter ended March 31, 2007 and for the period from December 27, 1993 through March 31, 2008, to change the accounting treatment of certain stock-based compensation of non-employees as required by applicable accounting guidance.

Statement of Financial Accounting Standards No. 123 (Revised 2004) Share-Based Payment ( SFAS 123R ) requires the use of the fair-value-based method to measure the value of stock-based compensation. In the Company's application of SFAS 123R, the Company took the position that an active market for its Common Stock did not exist for the first quarter of 2007, and that better information existed for the first quarter of 2007, due to the limited public float and trading volume in the market. The Company used alternative valuation methods to calculate the fair value of the Common Stock underlying

**Table of Contents**

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

**NOTE 2 RESTATEMENT OF CONSOLIDATED FINANCIAL STATEMENTS (Continued):**

certain stock-based compensation awards granted to non-employees during the first quarter of 2007. The alternative valuation methods included a retrospective valuation conducted by a third-party specialist in the first quarter. However, the Company concluded that it must rely on the traded market value of the Common Stock for the first and third quarters of 2007. The Company recalculated the compensation expense for non-employees for the first quarter of 2007 based on the traded market price of the Common Stock on the applicable measurement dates and determined that the resulting increase to the compensation expense for the period was material. On that basis, the Company recommended to the Audit Committee that a restatement is required.

SFAS 123R requires that share-based transactions with nonemployees to be measured based on the fair value of the goods or services received or the fair value of the equity instruments, whichever is more reliably measurable. EITF 96-18 specifies that the measurement date for such share-based transactions should be the earlier of (1) a performance commitment or (2) the date at which the counterparty's performance is complete. The Company had previously issued 2,148,569 shares of equity instruments (stock options and restricted Common Stock) whose terms indicated that performance was not complete until the applicable vesting requirements were fulfilled. Accordingly, the measurement of the share-based compensation expense was determined based on the fair value of those equity instruments at the end of the first quarter.

When preparing the consolidated financial statements for the first quarter of 2007, the Company's management utilized a fair value of its Common Stock of \$6.19 per share. The reported traded price of the Common Stock on the NYSE Alternext US was \$31.32 at the end of the first quarter of 2007. The Company has subsequently concluded that it should have used the reported traded price as the valuation methodology for equity instruments issued as compensation. Accordingly, the Company has restated the amounts previously reported for share-based compensation. The following is a summary of the effects of the restatement on the Company's consolidated financial statements (all amounts presented are in thousands, except per share data):

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2007 (unaudited)**

	As Reported	Adjustment	As Restated
Research and development Expenses, Net (1)	\$ 1,794	\$ 694	\$ 2,488
General and Administrative Expenses (2)	1,987	4,405	6,392
Operating Loss	3,781	5,099	8,880
Net Loss for the Period	3,450	5,099	8,549
Net Loss Per Share of Common Stock - Basic and Diluted	0.05	0.08	0.13
(1) Includes share-based compensation	206	694	900
(2) Includes share-based compensation	1,245	4,405	5,650

**Table of Contents**

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

**NOTE 2 RESTATEMENT OF CONSOLIDATED FINANCIAL STATEMENTS (Continued):  
CONSOLIDATED STATEMENTS OF CASH FLOWS FOR THE THREE MONTHS ENDED MARCH 31,  
2007 (unaudited)**

	As Reported	Adjustment	As Restated
Net loss for the period	\$(3,450)	\$(5,099)	\$(8,549)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Share based compensation	1,451	5,099	6,550

The restatement did not result in a change in the Company's previously reported cash flows from operating activities, or total cash and cash equivalents shown in the Company's consolidated financial statements for the three-month period ended March 31, 2007.

**NOTE 3 STOCK TRANSACTIONS**

- a. During the three months ended March 31, 2008, the Company issued 92,459 shares of Common Stock in connection with the exercise of 119,233 options by a certain officer and employees of the Company. The aggregate net exercise price was \$3.
- 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 in varying rates 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.



**Table of Contents**

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

**NOTE 4 COMMITMENTS**

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.

**NOTE 5 SUBSEQUENT EVENT**

In April 2008, the Company issued 15,148 shares of Common Stock in connection with the net exercise of options to purchase 15,835 shares of Common Stock by certain employees.

12

---

**Table of Contents**

**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 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 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.*

**Restatement**

On February 23, 2009, our management concluded, with the concurrence of the Audit Committee of our Board of Directors, or the Audit Committee, to amend and restate our financial statements for the year ended December 31, 2007, and each of the fiscal quarters of 2007. We have restated our consolidated balance sheet at December 31, 2007, statements of operations, changes in shareholders' equity and cash flows for the year ended December 31, 2007, the three months ended March 31, 2007 and for the period from December 27, 1993 through March 31, 2008, to change the accounting treatment of certain stock-based compensation of non-employees required by applicable accounting guidance Statement of Financial Accounting Standards No. 123 (Revised 2004) *Share-Based Payment*, or SFAS 123R. See Note 2 to the consolidated financial statements for further information.

All amendments and restatements to the financial statements are non-cash in nature.

SFAS 123R requires the use of the fair-value-based method to measure the value of stock-based compensation. In our application of SFAS 123R in the financial statements included in the Annual Report on Form 10-K for the year ended December 31, 2007 and the Quarterly Reports on Form 10-Q for the quarters ended March 31, 2007, June 30, 2007 and September 30, 2007, we took the position that an active market for our common stock did not exist for the first quarter of 2007, and that better information existed for the first and third quarters of 2007, due to the limited public float and trading volume in the market. We used alternative valuation methods to calculate the fair value of the common stock underlying certain stock-based compensation awards granted to nonemployees during the first and third quarters of 2007. We determined the fair value of stock-based compensation awards granted to nonemployees that vested during the first quarter of 2007 based on a retrospective valuation of our common stock conducted by a third-party specialist. Based on that valuation, we fixed the fair value of the common stock underlying stock-based compensation awards granted to nonemployees at March 31, 2007 at \$6.19 per share. For the second quarter of 2007, we used the traded market value of the common stock to calculate the fair value of the common stock underlying stock-based compensation awards granted to non-employees because we did not believe that there was a better alternative valuation mechanism available for that quarter. We determined that the fair value of the shares of common stock underlying stock-based compensation awards granted to nonemployees that vested during the third quarter of 2007 was \$5.00 per share, which was the public offering price of the common stock in the underwritten public offering we completed on October 25, 2007. However, we concluded that we must rely on the traded market value of the common stock. We recalculated the compensation expense for non-employees in 2007 based on the traded market price of the common stock on the applicable measurement dates and determined that the resulting increase to the compensation expense for the applicable periods was material. On that basis, we recommended to the Audit Committee that a restatement is required.

SFAS 123R requires that share-based transactions with nonemployees to be measured based on the fair value of the goods or services received or the fair value of the equity instruments, whichever is more reliably measurable. EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, specifies that the measurement date for such share-based transactions should be the earlier of (1) a performance commitment or (2) the date at which the counterparty's performance is complete. We had previously issued 2,148,569 shares of equity instruments (stock options and restricted common stock) whose terms indicated that performance was not complete until the applicable vesting requirements were fulfilled. Accordingly, the measurement of the share-based compensation expense was determined based on the fair value of those equity instruments at each quarterly vesting date.



## **Table of Contents**

### **Overview**

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx™ 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. In the third quarter of 2007, we initiated enrollment and treatment of patients in our phase III clinical trial of prGCD. 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, a medical treatment in which GCD is replaced in 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, an 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, 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, the 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, including 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 during the second half of 2008. Because these product candidates are based on well-understood proteins with known biological mechanisms of action, we believe we may be able to reduce the development risks and time to market for our product candidates. 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 prGCD and our other products, if approved, in North America, the European Union and in other significant markets, including Israel.

Our business is conducted by our wholly owned subsidiary, Protalix Ltd., which we acquired through a reverse merger transaction effective December 31, 2006. The accounting treatment for the merger transaction was a recapitalization 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 March 31, 2008, we had an accumulated deficit of \$57.7 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

**Table of Contents**

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 March 31, 2008 compared to the three months ended March 31, 2007***

***Research and Development Expenses***

Research and development expenses were \$4.3 million for the three months ended March 31, 2008, an increase of \$1.8 million, or 72%, from \$2.5 million for the three months ended March 31, 2007. The increase resulted primarily from the increase of \$2.8 million in salaries and materials associated with research and development. Such increase is mainly due to the costs incurred by us in connection with our phase III clinical trial of prGCD, which was commenced during the third quarter of 2007. The increase was partially offset by grants of \$1.4 million from the Office of the Chief Scientist, or the OCS, during the three months ended March 31, 2008, an increase of approximately \$628,000 compared to grants equal to \$738,000 received from the OCS during the three months ended March 31, 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.

***General and Administrative Expenses***

General and administrative expenses were \$2.0 million for the three months ended March 31, 2008, a decrease of \$4.4 million, or 69%, from \$6.4 million for the three months ended March 31, 2007. The decrease is mainly due to the decrease of 4.8 million in share based compensation resulting from 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 March 31, 2008.

***Financial Expenses and Income***

Financial income was \$1.2 million for the three months ended March 31, 2008, an increase of \$819,000, compared to \$331,000 for the three months ended March 31, 2007. The increase resulted primarily from a higher balance of cash and cash equivalents as of March 31, 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 New Israeli Shekel, or 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 \$14.2 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 are sufficient to satisfy our capital needs for the next 24 months.

**Table of Contents**

*Cash Flows*

Net cash used in operations was \$3.8 million for the three months ended March 31, 2008. The net loss for the three months ended March 31, 2008 of \$5.1 million was partially offset by \$2.2 million of non-cash share-based compensation but was increased due to an increase in accounts receivable of \$658,000 million, mainly due to grants to be received from the OCS. Net cash used in investing activities for the three months ended March 31, 2008 was \$856,000 and consisted primarily of purchases of property and equipment. Net cash used in financing activities for the three months ended March 31, 2008 was \$17,000, consisting of expenses paid during such period in connection with the October 2007 underwritten offering.

Net cash used in operations was \$2.9 million for the three months ended March 31, 2007. The net loss for the three months ended March 31, 2007 of \$8.5 million was partially offset by \$6.6 million of non-cash share-based compensation but was increased due to an increase in accounts receivable of \$886,000, mainly due to grants to be received from the OCS. Net cash used in investing activities for the three months ended March 31, 2007 was \$534,000 and consisted primarily of purchases of property and equipment. Net cash provided by financing activities for the three months ended March 31, 2007 was \$12.9 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, add infrastructure, and incur additional costs related to being a public company in the United States, including the costs of directors and officers insurance, investor relations programs and increased professional fees. In addition, we are considering a new manufacturing facility that would meet the FDA requirements 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 at least 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

**Table of Contents**

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 three months ended March 31, 2008 or the three months ended March 31, 2007.

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 three months ended March 31, 2008 or the three months ended March 31, 2007.

**Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of each of March 31, 2008 and March 31, 2007.

**Recently Issued Accounting Pronouncements**

In December 2007, 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 its parent company 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



**Table of Contents**

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. We are currently assessing the impact that EITF 07-01 may have on our results of operations and financial position.

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.

**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 New Israeli Shekels, 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:

	<b>Three months ended</b>		<b>Year ended</b>
	<b>March 31,</b>		<b>December</b>
	<b>2008</b>	<b>2007</b>	<b>2007</b>
Average rate for period	3.6234	4.2155	4.1081
Rate at period end	3.5530	4.1550	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.

**Table of Contents**

**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

**Table of Contents**

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 quarter ended March 31, 2008 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

**Management Consideration of Restatement**

On February 23, 2009, our management concluded, with the concurrence of the Audit Committee of our Board of Directors to amend and restate our financial statements for the year ended December 31, 2007, and the first three fiscal quarters of 2007 to change the accounting treatment of certain stock-based compensation of non-employees required by SFAS 123R for certain transactions with nonemployees. The change in accounting treatment affected our consolidated balance sheet at December 31, 2007, statements of operations, changes in shareholders' equity and cash flows for the year ended December 31, 2007, the quarters ended March 31, 2007 and September 30, 2007 and for the period from December 27, 1993 through September 30, 2008. As a result of the effect of the change in accounting treatment on our consolidated financial statements, we have restated our previously issued condensed consolidated financial statements for the year ended December 31, 2007 in our Annual Report on Form 10-K for the year ended December 31, 2008, and for each of the first three fiscal quarters of 2008.

In coming to the conclusion that our disclosure controls and procedures and our internal controls over financial reporting were effective as of the date of this Report, our management considered, among other things, its decision to restate our financial statements in connection with its calculation of stock-based compensation awards. Our Chief Executive Officer and Chief Financial Officer determined that they needed to change the accounting treatment. However, the need to restate our previously issued financial statements did not constitute a material weakness as of the date of this Report. They have determined that, as of the date of this Report, there were controls designed and in place to prevent or detect a material misstatement and therefore, there was no reasonable possibility that the computation of stock-based compensation awards will be materially misstated.

**Table of Contents**

**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 from the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2007.

**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 March 31, 2008, other than the issuance of 92,459 shares of common stock, in the aggregate, in connection with the exercise by a certain officer and employees of outstanding stock options granted under our 2006 Stock Incentive Plan for aggregate proceeds of approximately \$3,000. 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) 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 marketable securities. 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**

At our Annual Meeting of Shareholders held on January 31, 2008, the following matters were voted on by our shareholders: (i) the election of eight directors; and (ii) the approval of the appointment of Kesselman & Kesselman, Certified Public Accountant (Isr.), a member of PricewaterhouseCoopers International Limited, as our independent registered public accounting firm for the fiscal year ending December 31, 2007. The results of such shareholder votes are as follows:

**Table of Contents**

## (i) Election of Directors

	For	Withheld
Eli Hurvitz	50,252,375	218,325
David Aviezer, Ph.D., MBA	50,343,780	126,920
Yoseph Shaaltiel, Ph.D.	50,343,780	126,920
Alfred Akirov	50,343,780	126,920
Zeev Bronfeld	50,337,251	29,520
Yodfat Harel Gross	50,343,861	126,839
Eyal Sheratzky	50,345,913	124,787
Sharon Toussia-Cohen	50,337,251	133,449

(ii) Approval of Kesselman & Kesselman, Certified Public Accountant (Isr.), A member of PricewaterhouseCoopers International Limited, as our Independent Registered Public Accounting Firm

For	Against	Abstain
50,436,839	33,047	814

**Item 5. Other Information**

None.

**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	Bylaws of the Company, as amended	Incorporated by reference to the Company's Registration Statement on Form S-4 filed on March 26, 1998, SEC File No. 333-48677
31.1	Certification of Chief Executive Officer	Filed herewith



**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Method of Filing</b>
	pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	
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

**Table of Contents**

**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: March 6, 2009

By: /s/ David Aviezer

David Aviezer, Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: March 6, 2009

By: /s/ Yossi Maimon

Yossi Maimon  
Chief Financial Officer, Treasurer and  
Secretary  
(Principal Financial and Accounting  
Officer)

24