

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)

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

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):

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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 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 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.

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)

	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*
	2008	2007	2008	2007	through September 30, 2008
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 OTHER INCOME	(2,041)	(1,191) (6)	(222)	(685)	(4,489) (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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(a development stage company)

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS EQUITY

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

	Convertible 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
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
	2008	2007	
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

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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
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
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		Period from
	September 30,		December
	2008	2007	27,
			1993*
			through
			September
			30,
			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.

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PROTALIX BIOTHERAPEUTICS, INC.
(a development stage company)
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS