

Protalix BioTherapeutics, Inc.
Form 10-Q
August 03, 2009

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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 June 30, 2009

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
NYSE Amex**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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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 July 15, 2009, approximately 76,512,739 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, 2008, 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)

	June 30, 2009 (Unaudited)	December 31, 2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 29,132	\$ 42,596
Accounts receivable	1,945	793
Total current assets	31,077	43,389
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	650	581
PROPERTY AND EQUIPMENT, NET	10,458	6,841
Total assets	\$ 42,185	\$ 50,811
LIABILITIES AND SHAREHOLDERS EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$ 1,982	\$ 2,235
Other	4,232	3,292
Total current liabilities	6,214	5,527
LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT	1,056	937
Total liabilities	7,270	6,464
SHAREHOLDERS EQUITY	34,915	44,347
Total liabilities and shareholders equity	\$ 42,185	\$ 50,811

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

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

	Six Months Ended		Three Months Ended		Period
	June 30,	June 30,	June 30,	June 30,	from
	2009	2008	2009	2008	December
					27,
					1993*
					through
					June 30,
					2009
REVENUES					\$ 830
COST OF REVENUES					206
GROSS PROFIT					624
RESEARCH AND DEVELOPMENT EXPENSES (1)	\$ 11,296	\$ 9,684	\$ 6,210	\$ 4,031	65,713
less grants	(2,800)	(2,515)	(1,508)	(1,149)	(13,701)
	8,496	7,169	4,702	2,882	52,012
GENERAL AND ADMINISTRATIVE EXPENSES (2)	2,412	3,992	1,171	2,016	38,772
OPERATING LOSS	10,908	11,161	5,873	4,898	90,160
FINANCIAL INCOME NET	(298)	(1,819)	(446)	(669)	(4,503)
NET LOSS BEFORE CHANGE IN ACCOUNTING PRINCIPLE	10,610	9,342	5,427	4,229	85,657
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE					(37)
NET LOSS FOR THE PERIOD	\$ 10,610	\$ 9,342	\$ 5,427	\$ 4,229	\$ 85,620
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED:	\$ 0.14	\$ 0.12	\$ 0.07	\$ 0.06	
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:					
Basic and diluted	76,067,492	75,855,594	76,186,887	75,898,295	
(1) Includes share-based compensation	663	672	385	(655)	7,273
(2) Includes share-based compensation	501	1,495	317	648	23,346

* Incorporation
date. See Note
1a.

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

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

	Common Stock (2) 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, 2008:								
Common Stock and convertible preferred A, B and C shares and warrants issued for cash (net of issuance costs of \$5,078)	38,856,127	398,227	\$ 39	\$ 1	\$ 1,382	\$ 73,836		\$ 75,258
Exercise of options granted to employees and non-employees (includes Net Exercise)	2,948,420	847	3			413		416
Conversion of convertible preferred shares into common stock	24,375,870	(399,074)	24	(1)		(23)		
Change in accounting principle						(37)	\$ 37	
Expiration of warrants					(34)	34		
Merger with a wholly owned subsidiary of the Company (net of issuance cost of	583,280		1			240		241

\$642)					
Exercise of warrants	9,171,695	9	(1,348)	15,342	14,003
Restricted common stock issued for future services	2,667	*		8	8
Share-based compensation				29,468	29,468
Net loss for the period				(75,047)	(75,047)
Balance at December 31, 2008	75,938,059	76		119,281	(75,010) 44,347
Changes during the six month period ended June 30, 2009					
(Unaudited):					
Share-based compensation				1,164	1,164
Exercise of options granted to employees (includes Net Exercise)	439,680	*		14	14
Net loss for the period				(10,610)	(10,610)
Balance at June 30, 2009					
(Unaudited)	76,377,739	\$ 76		\$ 120,459	\$ (85,620) \$ 34,915

* Represents an amount less than \$1.

(1) Incorporation date. See Note 1a.

(2) Common Stock, \$0.001 par value; Authorized as of December 31, 2008 and June 30, 2009 -

150,000,000
shares.

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

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

	Six Months Ended June		Period from
	30,		December 27,
	2009	2008	1993*
			through
			June 30, 2009
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss for the period	\$ (10,610)	\$ (9,342)	\$ (85,620)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Cumulative effect of change in accounting principle			(37)
Share based compensation	1,164	2,167	30,619
Financial income, net (mainly exchange differences)	(77)	(916)	(1,153)
Depreciation and impairment of fixed assets	929	582	4,169
Changes in accrued liability for employee rights upon retirement	147	277	1,084
Gain on amounts funded in respect of employee rights upon retirement	(44)	(81)	(109)
Loss (Gain) on sale of fixed assets	2		(4)
Changes in operating assets and liabilities:			
Increase in accounts receivable	(1,062)	(388)	(1,571)
Increase in accounts payable and accruals	296	254	4,678
Net cash used in operating activities	\$ (9,255)	\$ (7,447)	\$ (47,944)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	\$ (4,226)	\$ (1,904)	\$ (13,419)
Investment grant received in respect of fixed assets			38
Investment in restricted cash deposit			(222)
Proceeds from sale of property and equipment	73		85
Amounts funded in respect of employee rights upon retirement	(39)	(81)	(555)
Net cash used in investing activities	\$ (4,192)	\$ (1,985)	\$ (14,073)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Loan and convertible bridge loan received			\$ 2,145
Repayment of loan			(1,000)
Issuance of shares and warrants, net of issuance cost		(56)	74,059
Exercise of options and warrants	\$ 8	\$ 3	14,427
			237

Merger with a wholly owned subsidiary of the Company, net of issuance cost

Net cash provided by (used in) financing activities	\$	8	\$	(53)	\$	89,868
EFFECT OF EXCHANGE RATE CHANGES ON CASH	\$	(25)	\$	1,032	\$	1,281
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		(13,464)		(8,453)		29,132
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD		42,596		61,813		
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	\$	29,132	\$	53,360	\$	29,132

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, except share data)
(Unaudited)

(Continued) 2

	Six Months Ended June 30,		Period from December 27, 1993* through June 30, 2009
	2009	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	\$ 1,327	\$ 752	\$ 1,327
Issuance cost not yet paid and accruals other	\$ 5	\$ 5	\$ 5
Issuance cost paid by a grant of options			\$ 21
Consultants and director credit balance converted into shares			\$ 80
Exercise of options granted to employees	\$ 6		\$ 6

* Incorporation date. See Note 1a.

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

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PROTALIX BIOTHERAPEUTICS, INC.

(a development stage company)

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

(Unaudited)

NOTE 1 SIGNIFICANT ACCOUNTING POLICIES

a. General

1. Operation