Protalix BioTherapeutics, Inc. Form 10-Q August 16, 2007

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)
x
QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACTOR 1934
For the quarterly period ended June 30, 2007
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 (I.R.S. Employer

Identification No.) of incorporation or organization)

2 Snunit Street

Science Park

POB 455

Carmiel, Israel 20100 (Zip Code)

(Address of principal executive office)

<u>972-4-988-9488</u>

(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 x No "

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

Large accelerated filer " Accelerated filer " Non-accelerated filer x

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

On August 13, 2007, approximately 65,665,181 shares of the Registrant s common stock, \$0.001 par value, were outstanding.

FORM 10-Q

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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 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 or or 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 FDA, or other regulatory authorities;

any lack of progress of our research and development (including the results of clinical trials being conducted by us);

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 financings 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 procedures in which our products are used;

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 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 our Annual Report on Form 10-K/A for the year ended December 31, 2006 and described from time to time in our future reports filed with the Securities and Exchange Commission. We undertake no obligation to update, and we do not have a policy of updating or revising, these forward-looking statements.

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PART I FINANCIAL INFORMATION

Item 1. Financial Statements

PROTALIX BIOTHERAPEUTICS, INC. (A development stage company) CONDENSED CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands)

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		December 31, 2006
(Uı	naudited)	
\$22,489		\$15,378
		7,577
2,277		1,336
24,766		24,291
346		293
3,248		2,404
\$28,360		\$26,988
LDERS EQUITY	<i>.</i>	
	\$867	\$892
	1,832	1,376
	\$22,489 2,277 24,766 346 3,248 \$28,360	2,277 24,766 346 3,248 \$28,360 LDERS EQUITY \$867

Liability for employee rights upon retirement

Total current liabilities

Total liabilities

LONG-TERM LIABILITY

		25,098	24,284
Total liabilities and shareholders	equity	\$28,360	\$26,988

2,699

563

3,262

2,268

436

2,704

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

SHAREHOLDERS EQUITY *

^{*} See Note 1a.

PROTALIX BIOTHERAPEUTICS, INC.

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

 $(U.S.\ dollars\ in\ thousands,\ except\ share\ and\ per\ share\ amounts)\\ (Unaudited)$

					Period from December 27, 1993*
	Six Mont	hs Ended	Three Mont	ths Ended	through
	June 30, 2007	June 30, 2006	June 30, 2007	June 30, 2006	June 30, 2007
REVENUES					\$ 830
COST OF REVENUES					206
GROSS PROFIT					624
RESEARCH AND DEVELOPMENT EXPENSES					
(1)	\$ 5,707	\$ 2,611	\$ 3,175	\$ 1,375	23,368
less - grants	(1,081)	(822)	(343)	(449)	(6,197)
	4,626	1,789	2,832	926	17,171
GENERAL AND ADMINISTRATIVE EXPENSES (2)	8,490	1,710	6,503	936	17,486
OPERATING LOSS	13,116	3,499	9,335	1,862	34,033
FINANCIAL (INCOME) EXPENSES NET	(506)	(35)	(175)	6	(874)
OTHER INCOME	(6)		(6)		(6)
NET LOSS BEFORE CHANGE IN					
ACCOUNTING PRINCIPLE	12,604	3,464	9,154	1,868	33,153
CUMULATIVE EFFECT OF					
CHANGE IN ACCOUNTING PRINCIPLE		(37)			(37)
NET LOSS FOR THE PERIOD					
	\$ 12,604	\$ 3,427	\$9,154	\$ 1,868	\$33,116

NET LOSS PER SHARE OF COMMON STOCK BASIC

AND DILUTED:

Prior to cumulative effect of change in accounting principle Cumulative effect of change in accounting principle	\$ 0.19	\$ 0.18 **	\$0.14	\$ 0.1	
	\$ 0.19	\$ 0.18	\$0.14	\$ 0.1	
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER COMMON STOCK:					
Basic and diluted	65,032,809	18,801,527	65,657,181	18,801,527	
(1) Includes share-based compensation(2) Includes share-based compensation	1,084 7,001	294 1,090	878 5,756	151 563	2,881 11,140

*

Incorporation date, see Note 1a.

**

Represents an amount less than \$0.01.

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	Convertible Preferred Shares of shares			nrrants	pai	tional id in pital unt	Deficit accumulate during developmen stage	
Balance at December 27, 1993 (1)									
Changes during the period from December 27, 1993 through December 31, 2006:									
Common Stock and convertible preferred A, B and C shares and warrants issued for cash (net of issuance	20.057.127	200 227	Ф20 Ф1		¢1 202		ф 2 0.14		ф 20.5 с 0
costs of \$768) Exercise of options granted to employees and non-employees	28,856,127 2,670,403	398,227 847	\$29 \$1		\$1,382		\$28,15		\$ 29,568 397
Conversion of	2,070,403	047	3				33	7 -1	391
convertible preferred shares into Common									
Stock	24,375,870	(399,074)	24 (1)			(23)			
Change in accounting principle						(37)		\$37	
Expiration of warrants Merger with a wholly owned subsidiary of the Company (net of	592.000			(34)				34	241
issuance cost of \$642) Exercise of warrants	583,086 5,296,279		1 5	(993)			24 9,65		241 8,670
Share-based compensation	3,270,217		J	(333)			5,95		5,957
Net loss for the period								(20,549)	(20,549)
Balance at December 31, 2006	61,781,765		62		355		44,37	79 (20,512)	24,284
Changes during the six month period ended June 30, 2007 (Unaudited):									
Share-based compensation							8,07	78	8,078

Exercise of warrants	3,875,416	-	4	(355)		5,684	5,333
Restricted Common							
Stock issued for services (3)	8,000		*			7	7
Net loss for the period	-	-	-	-	-	- (12,604)	(12,604)
Balance at June 30, 2007 (Unaudited)	65,665,181	-	\$66	-	-	\$ 58,148 \$ (33,116)	\$ 25,098

*

Represents an amount less than \$0.01.

(1)

Incorporation date, see Note 1a.

(2)

Common Stock, \$0.001 par value; Authorized as of December 31, 2006 and March 31, 2007 - 150,000,000 shares.

(3)

The Company issued a total of 8,000 restricted shares of Common Stock in respect of services provided by a member of the Company s Scientific Advisory Board (see also Note 2(d)).

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

PROTALIX BIOTHERAPEUTICS, INC.

(A development stage company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands) (Unaudited)

	Six Month	Period from December 27, 1993* through	
	June 30, 2007	June 30, 2006	June 30, 2007
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss for the period	\$ (12,604)	\$(3,427)	\$ (33,116)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Cumulative effect of change in accounting principle		(37)	(37)
Share based compensation	8,085	1,384	14,021
Depreciation and impairment of fixed assets	277	203	1,457
Changes in accrued liability for employee rights upon retirement	127	76	563
Loss (gain) on amounts funded in respect of employee rights upon retirement	(8)	9	(55)
Capital gain on fixed assets	(6)		