Protalix BioTherapeutics, Inc.
Form 10-Q
August 08, 2013

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 ACT OF 1934**

For the quarterly period ended June 30, 2013

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)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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 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 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 x

Non-accelerated filer ¨ (Do not check if a smaller reporting company) 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 x

On August 1, 2013, approximately 93,537,360 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" and "Management's Discussion and Analysis of Financial Condition and Results of Operations", 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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to our company or our subsidiaries 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 or revise, nor do we have a policy of updating or revising, 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:

- risks related to the commercialization efforts for taliglucerase alfa in the United States, Israel and Brazil;
- the risk of significant delays in the commercial introduction of taliglucerase alfa in other markets as planned;
- the risk that we will not be able to develop a successful sales and marketing organization for any of our product candidates in a timely manner, if at all;
- risks related to the acceptance and use of taliglucerase alfa or any of our product candidates, if approved, by physicians, patients and third-party payors;

- delays in the approval or the potential rejection of any application filed with or submitted to the regulatory authorities reviewing taliglucerase alfa outside of the United States, Israel, Brazil and other countries in which taliglucerase alfa is already approved;

- our ability to establish and maintain strategic license, collaboration and distribution arrangements, and to manage our relationships with Pfizer Inc., or Pfizer, Fundação Oswaldo Cruz or any other collaborator, distributor or partner;

- risks relating to our ability to finance our research programs, the expansion of our manufacturing capabilities and the ongoing costs in the case of delays in regulatory approvals for taliglucerase alfa outside of the United States, Israel, Brazil and other countries in which taliglucerase alfa is already approved;

- delays in our preparation and filing of applications for regulatory approval of our other product candidates in the United States, the European Union and elsewhere;

- our expectations with respect to the potential commercial value of our product and product candidates;

- the risk that products that are competitive to our product candidates may be granted orphan drug status in certain territories and, therefore, our product candidates may be subject to potential marketing and commercialization restrictions;

- the impact of the development of competing therapies and/or technologies;

- any lack of progress of our research and development activities and our clinical activities with respect to any product candidate;

- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;

- potential product liability risks, and risks of securing adequate levels of product liability and clinical trial insurance coverage;

- 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;

- risks relating to biosimilar legislation and/or healthcare reform in the United States, the European Union and elsewhere; 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 subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the U.S. Food and Drug Administration, or the FDA, or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

These forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These and other risks and uncertainties are detailed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2012, and are described from time to time in the reports we file with the Securities and Exchange Commission, or the Commission.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	June 30, 2013	December 31, 2012
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$33,126	$ 52,035
Accounts receivable - Trade	2,030	1,410
Other assets	3,585	3,686
Inventories	7,191	4,039
Total current assets	45,932	61,170
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,373	1,247
PROPERTY AND EQUIPMENT, NET	15,001	16,310
Total assets	$62,306	$ 78,727
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$3,944	$ 5,267
Other	13,681	11,051
Deferred revenues	9,003	9,437
Total current liabilities	26,628	25,755
LONG TERM LIABILITIES:		
Deferred revenues	45,115	48,888
Liability in connection with collaboration operation	376	5,425
Liability for employee rights upon retirement	2,173	2,016
Total long term liabilities	47,664	56,329
Total liabilities	74,292	82,084

COMMITMENTS		
CAPITAL DEFICIENCY	(11,986)	(3,357)
Total liabilities net of capital deficiency	$62,306	$ 78,727

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

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

	Six Months Ended		Three Months Ended	
	June 30, 2013	June 30, 2012	June 30, 2013	June 30, 2012
REVENUES	$5,832	$29,974	$2,264	$26,113
COMPANY'S SHARE IN COLLABORATION AGREEMENT	1,200	(988)	800	(855)
COST OF REVENUES	(2,289)	(4,599)	(1,318)	(3,279)
GROSS PROFIT	4,743	24,387	1,746	21,979
RESEARCH AND DEVELOPMENT EXPENSES (1)	(15,744)	(19,391)	(7,990)	(10,544)
Less – grant s and reimbursements	3,963	3,692	1,532	1,689
RESEARCH AND DEVELOPMENT EXPENSES, NET	(11,781)	(15,699)	(6,458)	(8,855)
GENERAL AND ADMINISTRATIVE EXPENSES (2)	(4,285)	(5,133)	(2,182)	(3,504)
OPERATING PROFIT (LOSS)	(11,323)	3,555	(6,894)	9,620
FINANCIAL INCOME – NET	165	183	57	22
NET PROFIT (LOSS) FOR THE PERIOD	$(11,158)	$3,738	$(6,837)	$9,642
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$(0.12)	$0.04	$(0.07)	$0.11
DILUTED	$(0.12)	$0.04	$(0.07)	$0.10
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNING				
(LOSS) PER SHARE:				
BASIC	92,241,505	89,702,496	92,297,522	91,526,224
DILUTED	92,241,505	92,670,033	92,297,522	94,881,167
(1) Includes share-based compensation	1,589	2,445	719	2,384
(2) Includes share-based compensation	910	1,314	413	1,246

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

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDER'S EQUITY (CAPITAL DEFICIENCY)

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

(Unaudited)

	Common Stock (1)	Common Stock	Additional paid–in capital	Accumulated deficit	Total
	Number of shares	Amount			
Balance at December 31, 2011	85,630,157	$86	$145,814	$(171,977)	$(26,077)
Changes during the six-month period ended June 30, 2012:					
Common stock issued for cash (net of issuance costs of $1,780)	5,175,000	5	25,383		25,388
Share-based compensation			3,759		3,759
Exercise of options granted to employees	1,117,249	1	1,054		1,055
Net profit for the period				3,738	3,738
Balance at June 30, 2012	91,922,406	$92	$176,010	$(168,239)	$7,863
Balance at December 31, 2012	93,489,809	$93	$180,145	$(183,595)	$(3,357)
Changes during the six-month period ended June 30, 2013:					
Share-based compensation related to stock options			645		645
Share-based compensation related to restricted stock award, net of forfeitures of 1,667 shares					