Protalix BioTherapeutics, Inc.
Form 10-Q
November 07, 2011

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 September 30, 2011

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	
(Address of principal executive offices)	20100 (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 November 1, 2011, approximately 85,623,627 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 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 us 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. 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:

- delays in the FDA's review of our response to the Complete Response Letter, or CRL, we received from the U.S. Food and Drug Administration, or FDA, relating to our New Drug Application (NDA) for taliglucerase alfa;
- delays in the approval or the potential rejection of any applications we file with the FDA or other regulatory authorities, including, with respect to our lead product candidate, taliglucerase alfa, the NDA we filed with the FDA and comparable filings and submissions made with the Israeli Ministry of Health, or Israeli MOH, and the European Medicines Agency, or the EMA, the National Sanitary Vigilance Agency, an agency of the Brazilian Ministry of Health, or ANVISA and the Australian Ministry of Health.
- risks relating to our ability to finance our ongoing costs in the case of delays in regulatory approvals for taliglucerase alfa;
- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;
- delays in our preparation and filing of applications for regulatory approval in the United States, the European Union, Israel, Brazil, Australia and elsewhere;
- any lack of progress of our research and development (including the results of our clinical trials);
- our ability to establish and maintain strategic license, collaboration and distribution arrangements and to manage our relationships with Pfizer Inc., or Pfizer, Teva Ltd. or with any other collaborator, distributor or partner;
- our ability to obtain on a timely basis sufficient patient enrollment in our clinical trials;
- the impact of development of competing therapies and/or technologies by other companies including risks relating to potential restrictions on the sale of some of our product candidates due to the orphan drug status that may be issued to competing products;
- risks relating to biogeneric legislation and/or healthcare reform in the United States or elsewhere;
- our ability to obtain additional financing required to fund our research programs and the expansion of our manufacturing capabilities;
- the risk that we will not be able to develop a successful sales and marketing organization for taliglucerase alfa in Israel or for any other product candidate in a timely manner, if at all;
- our ability to enter into supply arrangements with the Ministry of Health of Brazil or other parties and to supply drug product pursuant to such arrangements;
- 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 product candidates, 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; 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.

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" beginning Part II, Item 1A of this Quarterly Report on Form 10-Q, in our Annual Report on Form 10-K for the year ended December 31, 2010, Section 1A, under the heading "Risk Factors," in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2011, Part II, Item 1A, under the heading "Risk Factors," and as described from time to time in our future reports to be filed with the SEC.

Any or all of our 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.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2011 (Unaudited)	December 31, 2010
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 34,564	$ 35,900
Accounts receivable:		
Trade	2,276	7,013
Other	3,015	2,231
Inventories	427	1,189
Total current assets	40,282	46,333
LONG-TERM RECEIVABLES:		
Funds in respect of employee rights upon retirement	1,028	942
Deferred costs	1,009	
Total long term receivables	2,037	942
PROPERTY AND EQUIPMENT, NET	18,510	17,454
Total assets	$ 60,829	$ 64,729
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,955	$ 6,272
Other	7,726	8,068
Deferred revenues	5,633	4,563
Total current liabilities	18,314	18,903
LONG-TERM LIABILITIES:		
Deferred revenues	53,425	55,486
Long term payable	4,738	
Liability for employee rights upon retirement	1,705	1,663
Total long term liabilities	59,868	57,149
Total liabilities	78,182	76,052
COMMITMENTS		
CAPITAL DEFICIENCY	(17,353)	(11,323)
Total liabilities net of capital deficiency	$ 60,829	$ 64,729

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

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Nine Months Ended		Three Months Ended	
	September 30, 2011	September 30, 2010	September 30, 2011	September 30, 2010
REVENUES	$6,024	$ 5,466	$1,132	$ 3,184
COMPANY'S SHARE IN COLLABORATION AGREEMENT	(3,745)	(1,887)	(235)	(1,065)
COST OF REVENUES	(1,130)		(220)	
GROSS PROFIT	1,149	3,579	677	2,119
RESEARCH AND DEVELOPMENT EXPENSES (1)	(28,671)	(25,647)	(9,340)	(6,322)
less – grants and reimbursements	5,163	5,255	1,422	2,776
RESEARCH AND DEVELOPMENT EXPENSES, NET	(23,508)	(20,392)	(7,918)	(3,546)
GENERAL AND ADMINISTRATIVE EXPENSES (2)	(5,314)	(4,305)	(1,526)	(1,421)
OPERATING LOSS	(27,673)	(21,118)	(8,767)	(2,848)
FINANCIAL INCOME (EXPENSES)– NET	57	648	(108)	374
NET LOSS FOR THE PERIOD	$(27,616)	$ (20,470)	$(8,875)	$ (2,474)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED:	$0.33	$ 0.25	$0.10	$ 0.03
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE:				
Basic and diluted	84,351,420	80,879,843	85,585,777	80,914,930

(1) Research and development expenses include share-based compensation of $348 and $431 for the nine-month periods ended September 30, 2011 and September 30, 2010, respectively, and $92 and $213 for the three-month periods ended September 30, 2011 and September 30, 2010, respectively.

(2) General and administrative expenses include share-based compensation of $382 and $456 for the nine-month periods ended September 30, 2011 and September 30, 2010, respectively, and $117 and $142 for the three-month periods ended September 30, 2011 and September 30, 2010, respectively.

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

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY
(CAPITAL DEFICIENCY)
(U.S. dollars in thousands, except share data)

	Common Stock (1) Number	Common Stock	Additional paid–in capital	Accumulated deficit	Total
			Amount		
Balance at December 31, 2009	80,841,237	$81	$122,252	$ (106,450)	$15,883
Changes during the nine month period ended September 30, 2010 (Unaudited):					
Share-based compensation			$887		$887
Exercise of options granted to employees (includes Net Exercise)	172,300	*	159		159
Net loss for the period				(20,470)	(20,470)
Balance at September 30, 2010 (Unaudited)	81,013,537	$81	$123,298	$ (126,920)	$(3,541)
Balance at December 31, 2010	81,248,472	$81	$124,044	$ (135,448)	$(11,323)
Changes during the nine month period ended September 30, 2011 (Unaudited):					
Common stock issued for cash (net of issuance costs of $1,410) (see note 3a)	4,000,000	4	20,586		20,590
Share-based compensation			$730		$730
Exercise of options granted to employees and non-employees	350,045	1	265		266
Net loss for the period				(27,616)	(27,616)
Balance at September 30, 2011 (Unaudited)	85,598,517	$86	$145,625	$ (163,064)	$(17,353)

(1)Common Stock, $0.001 par value; Authorized – as of September 30, 2011, December 31, 2010 and September 30, 2010 - 150,000,000 shares.

* Represents an amount less than $1.

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

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

	Nine Months Ended	
	September 30, 2011	September 30, 2010
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(27,616)	$ (20,470)
Adjustments required to reconcile net loss to net cash used in operating activities		
Share based compensation	730	887
Depreciation and impairment of fixed assets	2,698	2,244
Financial expenses, net (mainly exchange differences)	156	(331)
Changes in accrued liability for employee rights upon retirement	115	330
Gain on amounts funded in respect of employee rights upon retirement	(12)	(16)
Loss on sale of fixed assets	2	11
Changes in operating assets and liabilities:		
Decrease in deferred revenues	(991)	(3,422)
Decrease (increase) in inventories	762	(6,702)
Decrease (increase) in accounts receivable	2,810	(5,097)
Increase in accounts payable and accruals	4,388	2,133
Net cash used in operating activities	$(16,958)	$ (30,433)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$(5,001	