Protalix BioTherapeutics, Inc.
Form 10-Q
August 09, 2018

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, 2018

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)

Delaware	**65-0643773**
(State or other jurisdiction	**(I.R.S. Employer**
of incorporation or organization)	**Identification No.)**

2 Snunit Street

Science Park

POB 455	**20100**

Carmiel, Israel
(Address of principal executive offices) **(Zip Code)**

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+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, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	¨	Accelerated filer	x
Non-accelerated filer			

¨ (Do not check if a smaller reporting company)

Smaller reporting company ¨ Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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, 2018, approximately 148,183,591 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" and "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 meanings of Section 27A of the Securities Act of 1933, as amended, 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," "potential," "predi "should," "will," "would" and words or phrases of similar import, as they relate to the 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:

- failure or delay in the commencement or completion of our preclinical studies and clinical trials, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; inability to monitor patients adequately during or after treatment; and or lack of sufficient funding to finance our clinical trials;

- the risk that the results of our clinical trials will not support the applicable claims of superiority, safety or efficacy and that our product candidates will not have the desired effects or will have undesirable side effects or other unexpected characteristics;

- risks relating to our ability to manage our relationship with Chiesi Farmaceutici S.p.A., or Chiesi, and any other collaborator, distributor or partner;

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- risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance or satisfy conversions of our outstanding convertible notes or any other indebtedness;

- risks relating to the compliance by Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health, or the Brazilian MoH, with its purchase obligations under our supply and technology transfer agreement, which may have a material adverse effect on us and may also result in the termination of such agreement;

- our dependence on performance by third-party providers of services and supplies, including without limitation, clinical trial services;

- risks relating to our ability to finance our activities and research programs;

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

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

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

- risks related to our supply of drug product to Pfizer Inc., or Pfizer, pursuant to our amended and restated exclusive license and supply agreement with Pfizer;

- risks related to the commercialization efforts for taliglucerase alfa in Brazil;

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

- 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 changes in healthcare laws, rules and regulations in the United States or 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, 2017, and are described from time to time in the reports we file with the U.S. 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, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$28,327	$51,163
Accounts receivable – Trade	5,248	1,721
Other assets	2,499	1,934
Inventories	6,978	7,833
Total current assets	$43,052	$62,651
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,729	1,887
PROPERTY AND EQUIPMENT, NET	6,940	7,676
Total assets	$51,721	$72,214
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$6,001	$7,521
Other	9,071	9,310
Convertible notes		5,921
Total current liabilities	$15,072	$22,752
LONG TERM LIABILITIES:		
Convertible notes	46,742	46,267
Deferred revenues	31,885	26,851
Liability for employee rights upon retirement	2,335	2,586
Other long term liabilities	5,258	5,051
Total long term liabilities	$86,220	$80,755

Total liabilities	$101,292	$103,507
COMMITMENTS		
CAPITAL DEFICIENCY	(49,571)	(31,293)
Total liabilities net of capital deficiency	$51,721	$72,214

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 and per share data)
(Unaudited)

	Six Months Ended		Three Months Ended	
	June 30, 2018	June 30, 2017	June 30, 2018	June 30, 2017
REVENUES	$6,559	$9,247	$2,006	$6,358
COST OF REVENUES	(5,107)	(7,611)	(2,183)	(5,523)
GROSS PROFIT (LOSS)	1,452	1,636	(177)	835
RESEARCH AND DEVELOPMENT EXPENSES (1)	(14,762)	(15,271)	(7,476)	(9,304)
Less – grants	1,078	1,816	235	478
RESEARCH AND DEVELOPMENT EXPENSES, NET	(13,684)	(13,455)	(7,241)	(8,826)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(4,656)	(5,351)	(2,158)	(2,814)
OPERATING LOSS	(16,888)	(17,170)	(9,576)	(10,805)
FINANCIAL EXPENSES	(4,013)	(5,132)	(1,793)	(3,045)
FINANCIAL INCOME	207	1,665	75	40
(LOSS) INCOME FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE		(38,061)		14,260
FINANCIAL (EXPENSES) INCOME, NET	(3,806)	(41,528)	(1,718)	11,255
NET (LOSS) INCOME FOR THE PERIOD	$(20,694)	$(58,698)	$(11,294)	$450
NET (LOSS) EARNINGS PER SHARE OF COMMON STOCK:				
BASIC				
Net (loss) earnings per share of common stock	$(0.14)	$(0.47)	$(0.08)	$0.00
DILUTED				
Net loss per share of common stock	$(0.14)	$(0.47)	$(0.08)	$(0.06)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING (LOSS) EARNINGS PER SHARE				
BASIC	145,985,445	126,000,782	146,644,450	127,523,706
DILUTED	145,985,445	126,000,782	146,644,450	192,598,389
(1) Includes share-based compensation	$40	$120	$(2)	$55
(2) Includes share-based compensation	$34	$96	$14	$43

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

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PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN 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, 2016	124,134,085	$124	$202,575	$ (212,656)	$(9,957)
Changes during the six-month period ended June 30, 2017:					
Share-based compensation related to stock options			216		216
Reclassification of embedded derivative			43,634		43,634
Convertible notes conversions	4,948,821	5	4,132		4,137
Net loss for the period				(58,698)	(58,698)
Balance at June 30, 2017	129,082,906	129	250,557	(271,354)	(20,668)
Balance at December 31, 2017	143,728,797	$144	$266,495	$ (297,932)	$(31,293)
Changes during the six-month period ended June 30, 2018:					
Share-based compensation related to stock options			58		58
Share-based compensation related to restricted stock award	29,898	*	16		16
Convertible notes conversions	1,811,260	2	1,190		1,192
Convertible notes exchange	2,613,636	2	1,148		1,150
Net loss for the period				(20,694)	(20,694)
Balance at June 30, 2018	148,183,591	$148	$268,907	$ (318,626)	$(49,571)

*Represents an amount less than $1.

(1)Common Stock, $0.001 par value; Authorized – as of June 30, 2018 and 2017 - 250,000,000.

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)

(Unaudited)