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, 2017

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 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 ☒ 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 ☐

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	☒
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 ☒

On November 1, 2017, approximately 139,727,673 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 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," "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 ultimate timing and purchase of alfataliglicerase by Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health, or the Brazilian MoH, pursuant to the stated purchase intentions of the Brazilian MoH of the stated amounts, if at all;
- risks related to the successful conclusion of our negotiations with the Brazilian MoH regarding the future purchase of alfataliglicerase;
- 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 and manage our relationship with Chiesi Farmaceutici S.p.A., or Chiesi, and any other collaborator, distributor or partner;
- 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 our ability to defease the remaining outstanding 4.5% convertible notes due September 2018 on or prior to June 16, 2018;
- risks relating to the compliance by Fiocruz with its purchase obligations under our supply and technology transfer agreement, which may result in the termination of such agreement which may have a material adverse effect on our company;
- the risk that we will not be able to develop a successful sales and marketing organization for taliglucerase alfa in Brazil, or for any other product candidate, in a timely manner, if at all;
- 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 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 supply of drug product to Fiocruz pursuant to our supply arrangement with Fiocruz;
- 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, 2016, 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)

	September 30, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,482	$ 63,281
Accounts receivable – Trade	7,292	693
Other assets	2,689	2,321
Inventories	7,479	5,245
Assets of discontinued operation	211	327
Total current assets	$ 51,153	$ 71,867
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,919	1,677
PROPERTY AND EQUIPMENT, NET	7,986	8,703
Total assets	$ 61,058	$ 82,247
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 8,691	$ 4,007
Other	11,989	7,496
Convertible notes	5,911	53,872
Deferred revenues		837
Total current liabilities	$ 26,591	$ 66,212
LONG TERM LIABILITIES:		
Convertible notes	53,625	19,343
Liability for employee rights upon retirement	2,612	2,348
Promissory note	4,301	4,301
Total long term liabilities	$ 60,538	$ 25,992
Total liabilities	$ 87,129	$ 92,204
COMMITMENTS		
CAPITAL DEFICIENCY	(26,071)	(9,957)
Total liabilities net of capital deficiency	$ 61,058	$ 82,247

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)

	Nine Months Ended		Three Months Ended	
	September 30, 2017	**September 30, 2016**	**September 30, 2017**	**September 30, 2016**
REVENUES	$ 16,773	$ 7,118	$ 7,526	$ 4,670
COST OF REVENUES	(13,677)	(6,446)	(6,066)	(4,248)
GROSS PROFIT	3,096	672	1,460	422
RESEARCH AND DEVELOPMENT EXPENSES (1)	(22,389)	(23,700)	(7,118)	(6,353)
Less – grants	2,545	4,800	729	1,297
RESEARCH AND DEVELOPMENT EXPENSES, NET	(19,844)	(18,900)	(6,389)	(5,056)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(8,187)	(6,215)	(2,836)	(2,014)
OPERATING LOSS	(24,935)	(24,443)	(7,765)	(6,648)
FINANCIAL EXPENSES	(8,809)	(2,715)	(3,680)	(910)
FINANCIAL INCOME	1,670	606	8	268
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE	(38,061)			
FINANCIAL EXPENSES, NET	(45,200)	(2,109)	(3,672)	(642)
LOSS FROM CONTINUING OPERATIONS	(70,135)	(26,552)	(11,437)	(7,290)
LOSS FROM DISCONTINUED OPERATIONS	-	(189)	-	-
NET LOSS FOR THE PERIOD	$ (70,135)	$ (26,741)	$ (11,437)	$ (7,290)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED				
Loss from continuing operations	(0.55)	(0.27)	(0.09)	(0.07)
Loss from discontinued operations		(0.00)		
Net loss per share of common stock	$ (0.55)	$ (0.27)	$ (0.09)	$ (0.07)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	128,223,722	99,766,245	132,549,001	99,821,970
(1) Includes share-based compensation	$ 163	$ 448	$ 43	$ 82
(2) Includes share-based compensation	$ 128	$ 317	$ 32	$ 81

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

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' 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, 2015	**99,800,397**	**$ 100**	**$ 194,064**	**$ (183,291)**	**$ 10,873**
Changes during the nine-month period ended September 30, 2016:					
Share-based compensation related to stock options			697		697
Share-based compensation related to restricted stock award	7,843		68		68
Exercise of options	122,162	*	*		*
Net loss from continuing operations				(26,552)	(26,552)
Net loss from discontinued operations				(189)	(189)
Balance at September 30, 2016	**99,930,402**	**100**	**194,829**	**(210,032)**	**(15,103)**
Balance at December 31, 2016	**124,134,085**	**$ 124**	**$ 202,575**	**$ (212,656)**	**$ (9,957)**
Changes during the nine-month period ended September 30, 2017:					
Share-based compensation related to stock options			291		291
Reclassification of embedded derivative			43,634		43,634
Convertible notes conversions	9,711,235	10	8,771		8,781
Conversion component related to convertible notes issuance			1,315		1,315
Net loss from continuing operations				(70,135)	(70,135)
Balance at September 30, 2017	**133,845,320**	**$ 134**	**$ 256,586**	**$ (282,791)**	**$ (26,071)**

* Represents an amount less than $1.

(1) Common Stock, $0.001 par value; Authorized – as of September 30, 2017 and 2016 - 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)

	Nine months ended	
	September 30, 2017	**September 30, 2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (70,135)	$ (26,741)
Loss from discontinued operations		(189)
Loss from continuing operations	(70,135)	(26,552)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	291	765
Depreciation	1,469	1,489
Financial (income) expenses, net (mainly exchange differences)	13	(375)
Changes in accrued liability for employee rights upon retirement	54	(31)
Gain on amounts funded in respect of employee rights upon retirement	(21)	(3)
Loss on conversion of convertible notes	587	-
Change in fair value of convertible notes embedded derivative	38,061	-
Amortization of debt issuance costs and debt discount	1,710	333
Issuance of shares for interest payment in connection with conversions of convertible notes	1,111	-
Changes in operating assets and liabilities:		
Decrease in deferred revenues	(837)	(291)
Increase in accounts receivable and other assets	(6,467)	(1,358)
Decrease (increase) in inventories	(2,234)	907
Increase in accounts payable and accruals	8,698	367
Net cash used in continuing operations	(27,700)	(24,749)
Net cash provided by (used in) discontinued operations	116	(11)
Net cash used in operating activities	$ (27,584)	$ (24,760)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (681)	$ (732)
Increase in restricted deposit	(336)	
Amounts funded in respect of employee rights upon retirement, net	(68)	7
Net cash used in investing activities	$ (1,085)	$ (725)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net payment for conversion of convertible notes	(10,961)	-
Net proceeds from issuance of convertible notes	9,542	-
Net cash used in financing activities	(1,419)	-
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ 289	$ 431
NET DECREASE IN CASH AND CASH EQUIVALENTS	(29,799)	(25,054)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	63,281	76,374
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 33,482	$ 51,320

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)

(Continued) – 2

	Nine months ended	
	September 30, 2017	**September 30, 2016**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 666	$ 642
Convertible notes conversions	$ 7,668	-
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$ 2,613	$ 3,105

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

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the "Company"), and its wholly-owned subsidiaries, Protalix Ltd. and Protalix B.V. (the "Subsidiaries"), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company's proprietary ProCellEx® protein expression system ("ProCellEx"). To date, the Company has successfully developed taliglucerase alfa (marketed under the name Uplyso™ in Brazil and certain other Latin American countries and Elelyso® in the rest of the territories) for the treatment of Gaucher disease that has been approved for marketing in the United States, Brazil, Israel and other markets. The Company has a number of product candidates in varying stages of the clinical development process. The Company's current strategy is to develop proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications.

The Company's product pipeline currently includes, among other candidates:

(1) pegunigalsidase alfa, or PRX-102, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder;

(2) alidornase alfa, or PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or DNase, under development for the treatment of Cystic Fibrosis, to be administered by inhalation; and

(3) OPRX-106, the Company's oral antiTNF product candidate which is being developed as an orally-delivered anti-inflammatory treatment using plant cells as a natural capsule for the expressed protein.

Obtaining marketing approval with respect to any product candidate in any country is directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain such approvals. The Company cannot reasonably predict the outcome of these activities.

Since its approval by the FDA, taliglucerase alfa has been marketed mainly in the United States by Pfizer as provided in the exclusive license and supply agreement by and between Protalix Ltd. and Pfizer, which is referred to herein as the Pfizer Agreement. In October 2015, the Company entered into an Amended and Restated Exclusive License and Supply Agreement (the "Amended Pfizer Agreement") which amends and restates the Pfizer Agreement in its entirety. Pursuant to the Amended Pfizer Agreement, the Company sold to Pfizer its share in the collaboration created under the Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36.0 million. As part of the sale, the Company agreed to transfer its rights to Elelyso in Israel to Pfizer while gaining full rights to it in Brazil. Under the Pfizer Agreement, Pfizer and the Company shared revenues and expenses for the development and commercialization of Elelyso on a 60%/40% basis globally, excluding Israel and Brazil. Under the Amended Pfizer Agreement, Pfizer is entitled to all of the revenues, and is responsible for 100% of expenses globally for Elelyso, excluding Brazil where the Company is responsible for all expenses and retains all revenues.

On June 18, 2013, the Company entered into a Supply and Technology Transfer Agreement (the "Brazil Agreement") with Fiocruz, an arm of the Brazilian MoH, for taliglucerase alfa. Fiocruz's purchases of Uplyso to date have been significantly below certain agreed upon purchase milestones and, accordingly, the Company has the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, the Company is, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. The Company is discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, the Company will determine what it believes to be the course of action that is in the best interest of the Company.

NOTE 1 – SIGNIFICANT ACCOUNTING POLICIES (continued)**:**

In 2017, the Company received a purchase order from the Brazilian MoH for the purchase of approximately $24.3 million of alfataliglicerase for the treatment of Gaucher patients in Brazil. The purchase order consists of a number of shipments in increasing volumes. Shipments started in June 2017.

Based on its current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least 12 months, although no assurance can be given that it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, the Company may need to seek additional financing.

b. Basis of presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for annual financial statements. In the opinion of management, all adjustments (of a normal recurring nature) considered necessary for a fair statement of the results for the interim periods presented have been included. Operating results for the interim period are not necessarily indicative of the results that may be expected for the full year.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2016, filed by the Company with the Commission. The comparative balance sheet at December 31, 2016 has been derived from the audited financial statements at that date.

c. Net loss per share

Basic and diluted loss per share ("LPS") are computed by dividing net loss by the weighted average number of shares of the Company's Common Stock, par value $0.001 per share (the "Common Stock"), outstanding for each period.

Diluted LPS is calculated in continuing operations. The calculation of diluted LPS does not include 19,572,040 and 76,195,921 shares of Common Stock underlying outstanding options and restricted shares of Common Stock and shares issuable upon conversion of the convertible notes for the nine months ended September 30, 2016 and 2017, respectively, and 19,484,667 and 80,696,070 shares of Common Stock for the three months ended September 30, 2016 and 2017, respectively, because the effect would be anti-dilutive.

NOTE 2 – INVENTORIES

Inventory at September 30, 2017 and December 31, 2016 consisted of the following:

	September 30, 2017	December 31, 2016
	(U.S. dollars in thousands)	
Raw materials	$ 4,153	$ 2,591
Work in progress	492	395
Finished goods	2,834	2,259
Total inventory	$ 7,479	$ 5,245

NOTE 3 – FAIR VALUE MEASUREMENT

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received from the sale of an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The fair value of the financial instruments included in the working capital of the Company is usually identical or close to their carrying value.

The fair value of the convertible notes derivative is based on Level 3 measurement.

As of September 30, 2017, the fair value of the remaining $5.9 million in aggregate principal amount of the Company's outstanding 4.5% convertible promissory notes due 2018, of the remaining $61.9 million in aggregate principal amount of the Company's outstanding 7.5% secured convertible promissory notes due 2021, and $5.0 million in aggregate principal amount of the Company's outstanding 4.5% convertible promissory notes due 2022, is approximately $5.6 million, $76.9 million and $5.3 million, respectively, based on a Level 3 measurement. See note 5 for the parameters used in the valuation of fair value.

NOTE 4 – DISCONTINUED OPERATIONS

The Company accounted for the termination of the Pfizer Agreement and the sale of the license as a discontinued operation, in accordance with ASU No. 2014-08. The following assets and liabilities associated with the Company's discontinued operations have been segregated and classified as assets and liabilities of discontinued operations, as appropriate, in the consolidated balance sheets as of September 30, 2017 and December 31, 2016, respectively:

	September 30, 2017	December 31, 2016
	(*U.S. dollars in thousands*)	
CURRENT ASSETS:		
Accounts receivable - Trade	$ 211	$ 327
Total current assets of discontinued operations	$ 211	$ 327

NOTE 4 – DISCONTINUED OPERATIONS (continued)**:**

The following summarizes financial information related to the Company's discontinued operations in the Company's consolidated statements of operations for the nine months ended September 30, 2017 and September 30, 2016:

	Nine months ended September 30,	
	2017	**2016**
	(U.S. dollars in thousands)	
REVENUES		$ 209
COST OF REVENUES		(373)
GROSS LOSS		(164)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES		(25)
NET LOSS FOR THE PERIOD FROM DISCONTINUED OPERATIONS	-	$ (189)

NOTE 5 – CONVERTIBLE NOTES

On July 24, 2017, the Company entered into a Note Purchase Agreement with certain institutional investors relating to the private issuance and sale by the Company of $10 million in aggregate principal amount of its 7.5% secured convertible promissory notes due 2021. The 7.5% convertible notes were issued pursuant to the base indenture dated December 7, 2016 (the existing 7.5% convertible notes).

Concurrently with the consummation of the purchase described in the Note Purchase Agreement, the Company entered into a privately negotiated exchange agreement with certain of its existing note holders to exchange $9.0 million in aggregate principal amount of the Company's 4.5% convertible notes due 2018 for $8.55 million in aggregate principal amount of 4.5% convertible notes due 2022 (the "2017 Exchange Agreement").

All of the Company's outstanding convertible notes are accounted for using the guidance set forth in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification (ASC) 815 requiring that the Company determine whether the embedded conversion option must be separated and accounted for separately. ASC 470-20 regarding debt with conversion and other options requires the issuer of a convertible debt instrument that may be settled in cash upon conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer's nonconvertible debt borrowing rate. The Company accounts for the 4.5% convertible notes due 2018, and for the 4.5% convertible notes due 2022, as a liability, on an aggregated basis, in their entirety. The conversion feature for the Company's existing 7.5% convertible notes is accounted for as a derivative which is bifurcated from the debt host contract and is measured at fair value through the statement of operations. On April 12, 2017, the Company received approval from its stockholders to issue shares of the Company's Common Stock in excess of 19.9% of the Company's outstanding shares of Common Stock to settle conversion requests and pay interest on the Company's issued 7.5% convertible notes. As a result, the Company reclassified the embedded derivative to equity. During the nine months ended September 30, 2017 such measurement of the derivative resulted in a non-cash charge to the Company's statement of operations of $38,061 thousand. The conversion feature of the 7.5% convertible notes issued in July 2017 is accounted for as equity, which is bifurcated from the debt host contract.

As the terms of the 4.5% convertible notes due 2018 and the 4.5% convertible notes due 2022 are substantially different, the 2017 Exchange Agreement was considered an extinguishment of debt, where the Company used fair value method to account for the 4.5% convertible notes due 2022. The Company recognized a loss of $1.3 million due to the extinguishment.

NOTE 5 – CONVERTIBLE NOTES (continued)**:**

The debt discount and debt issuance costs regarding the issuance of the Company's outstanding 4.5% convertible notes due 2018 are deferred and amortized over the applicable convertible period.

Issuance costs regarding the issuance of the Company's 7.5% convertible notes were allocated to the liability, equity component, derivative and shares of Common Stock based on their relative fair values. Issuance costs regarding the issuance of the Company's 4.5% convertible notes due 2022 were allocated to the liability.

Issuance costs that were allocated to liability will be amortized using the effective interest rate, other than issuance costs that were allocated to derivative, which were expensed immediately.

During the nine months ended September 30, 2017, note holders converted (i) approximately $10.8 million in aggregate principal amount of the Company's 7.5% convertible notes into a total of 5,044,484 shares of Common Stock and cash payments equal to approximately $11.0 million and (ii) approximately $3.55 million in aggregate principal amount of the Company's 4.5% convertible notes due 2022 into a total of 4,666,751 shares of Common Stock.

The Company prepared a valuation of the fair value of the 4.5% convertible notes due 2018, for the 4.5% convertible notes due 2022 and for the 7.5% convertible notes due 2021 (a Level 3 valuation) as of September 30, 2017. The value of these notes were estimated by implementing the binomial model. The liability component was valued based on the Income Approach. The following parameters were used:

(U.S. Dollars in thousands)	**4.5% notes due 2018**	**4.5% notes due 2022**	**7.5% notes due 2021**
Stock price (USD)	0.58	0.58	0.58
Expected term	0.96	4.38	4.13
Risk free rate	1.33%	1.87%	1.83%
Volatility	103.71%	64.73%	66.34%
Yield	11.87%	14.22%	11.30%

NOTE 6 – SUBSEQUENT EVENTS

On October 18, 2017, holders of the Company's 4.5% convertible notes due 2022 converted all of the remaining $5.0 million face value of the notes in exchange for 5,882,353 shares of Common Stock. Additional shares will be issued in connection with the make-whole premium associated with the converted notes.

On October 17, 2017, Protalix Ltd. entered into an Exclusive License and Supply Agreement with Chiesi, or the Chiesi Agreement, with respect to the development and commercialization of pegunigalsidase alfa, or PRX-102. Under the terms of the Chiesi Agreement, Protalix Ltd. granted to Chiesi exclusive licensing rights for the commercialization of PRX-102 for all markets outside of the United States. Protalix Ltd. maintains the exclusive commercialization rights to PRX-102 in the United States. Protalix Ltd. is entitled to an upfront, non-refundable, non-creditable payment of $25 million from Chiesi in consideration for and as reimbursement of the costs sustained by Protalix Ltd. up to the effective date of the Chiesi Agreement and additional payments of up to $25 million to cover development costs for PRX-102, subject to a maximum of $10 million per year. Protalix Ltd. is also eligible to receive up to an additional $320 million in regulatory and commercial milestone payments. Chiesi will also make tiered payments of 15% to 35% of its net sales to Protalix Ltd., depending on the amount of annual sales, as consideration for the supply of PRX-102.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the consolidated financial statements and the related notes included elsewhere in this Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2016. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx® protein expression system. We developed our first commercial drug product, Elelyso®, using our ProCellEx system and we are now focused on utilizing the system to develop a pipeline of proprietary, clinically superior versions of recombinant therapeutic proteins that primarily target large, established pharmaceutical markets and that in most cases rely upon known biological mechanisms of action. With our experience to date, we believe ProCellEx will enable us to develop additional proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications. We are now also applying the unique properties of our ProCellEx system for the oral delivery of therapeutic proteins.

On May 1, 2012, the FDA approved for sale our first commercial product, taliglucerase alfa for injection, an enzyme replacement therapy, or ERT, for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Subsequently, taliglucerase alfa was approved for marketing by the regulatory authorities of other countries. Taliglucerase alfa is called alfataliglicerase in Brazil and certain other Latin American countries, where it is marketed under the name Uplyso™. Taliglucerase alfa is marketed under the name Elelyso in other territories.

Since its approval by the FDA, taliglucerase alfa has been marketed mainly in the United States by Pfizer, as provided in the exclusive license and supply agreement by and between Protalix Ltd., our wholly-owned subsidiary, and Pfizer, which we refer to as the Pfizer Agreement. In October 2015, we entered into an Amended and Restated Exclusive License and Supply Agreement, or the Amended Pfizer Agreement, which amends and restates the Pfizer Agreement in its entirety. Pursuant to the Amended Pfizer Agreement, we sold to Pfizer our share in the collaboration created under the initial Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36.0 million. As part of the sale, we agreed to transfer our rights to Elelyso in Israel to Pfizer, while gaining full rights to Elelyso in Brazil. We will continue to manufacture drug substance for Pfizer, subject to certain terms and conditions. Under the initial Pfizer Agreement, Pfizer shared revenues and expenses for the development and commercialization of Elelyso with us on a 60%/40% basis globally, excluding Israel and Brazil. Under the Amended Pfizer Agreement, Pfizer is responsible for 100% of expenses, and entitled to all revenues globally for Elelyso, excluding Brazil, where we are responsible for all expenses and retain all revenues.

For the first 10-year period after the execution of the Amended Pfizer Agreement, we have agreed to sell drug substance to Pfizer for the production of Elelyso, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods subject to certain terms and conditions. Any failure to comply with our supply commitments may subject us to substantial financial penalties, which will have a material adverse effect on our business, results of operations and financial condition. The Amended Pfizer Agreement also includes customary provisions regarding cooperation for regulatory matters, patent enforcement, termination, indemnification and insurance requirements.

On June 18, 2013, we entered into a Supply and Technology Transfer Agreement, or the Brazil Agreement, with Fiocruz, an arm of the Brazilian MoH, for taliglucerase alfa.

In 2017, we received a purchase order from the Brazilian MoH for the purchase of approximately $24.3 million of alfataliglicerase for the treatment of Gaucher patients in Brazil. The purchase order consists of a number of shipments in increasing volumes. Shipments started in June 2017. Fiocruz's purchases of Uplyso to date have been significantly below certain agreed upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding the low purchase amounts, we are, at this time, continuing to supply Uplyso to Fiocruz under the Brazil Agreement, and patients continue to be treated with Uplyso in Brazil. We are discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, we will determine what we believe to be the course of action that is in the best interest of our company.

We are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates:

(1) pegunigalsidase alfa, or PRX-102, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, currently in an ongoing phase III clinical trials.

(2) alidornase alfa, or PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or DNase, under development for the treatment of Cystic Fibrosis, to be administered by inhalation. alidornase alfa has successfully completed a phase II efficacy and safety study.

(3) OPRX-106, our oral antiTNF product candidate which is being developed as an orally-delivered anti-inflammatory treatment using plant cells as a natural capsule for the expressed protein. Patient enrollment in our phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis was initiated in the fourth quarter of 2016.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Brazil), which we licensed to Pfizer, and rights for pegunigalsidase outside the United States, which we licensed to Chiesi, we hold the worldwide commercialization rights to all of our proprietary development candidates. In addition, we continuously evaluate potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutes.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing in this Quarterly Report. There have not been any changes to our significant accounting policies since the Annual Report on Form 10-K for the year ended December 31, 2016.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Convertible Notes

All outstanding convertible notes are accounted for using the guidance set forth in the Financial Accounting Standards Board, or FASB, Accounting Standards Codification (ASC) 815 requiring that we determine whether the embedded conversion option must be separated and accounted for separately. ASC 470-20 regarding debt with conversion and other options requires the issuer of a convertible debt instrument that may be settled in cash upon conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer's nonconvertible debt borrowing rate. We account for the 4.5% convertible notes due 2018, and the 4.5% convertible notes due 2022, as a liability, on an aggregated basis, in their entirety. The conversion feature for our 7.5% convertible notes issued in December 2016, is accounted for as a derivative which is bifurcated from the debt host contract and is measured at fair value through the statement of operations. On April 12, 2017, we received approval from our stockholders to issue shares of our common stock in excess of 19.9% of our outstanding shares of common stock to settle conversion requests and pay interest on our issued 7.5% convertible notes. As a result, we reclassified the embedded derivative to equity. The conversion feature of the 7.5% convertible notes issued in July 2017 is accounted for as equity.

As the terms of the 4.5% convertible notes due 2018 and the 4.5% convertible notes due 2022 are substantially different, the 2017 Exchange Agreement was considered an extinguishment of debt, where we used fair value to account for the 4.5% convertible notes due 2022. We recognized a loss of $1.3 million due to the extinguishment.

The debt discount and debt issuance costs regarding the issuance of our 4.5% convertible notes due 2018 are deferred and amortized over the applicable convertible period.

Issuance costs regarding the issuance of our 7.5% convertible notes were allocated to the liability, equity component, derivative and shares of common stock based on their relative fair values. Issuance costs regarding the issuance of our 4.5% convertible notes due 2022 were allocated to the liability. Issuance costs that were allocated to liability will be amortized using the effective interest rate, other than issuance costs that were allocated to derivative, which were expensed immediately.

During the nine months ended September 30, 2017, note holders converted (i) approximately $10.8 million in aggregate principal amount of our 7.5% convertible notes into a total of 5,044,484 shares of our common stock and cash payments equal to approximately $11.0 million and (ii) approximately $3.55 million in aggregate principal amount of our 4.5% convertible notes due 2022 into a total of 4,666,751 shares of our common stock.

Results of Operations

Three months ended September 30, 2017 compared to the three months ended September 30, 2016

Revenues

We recorded revenues of $7.5 million during the three months ended September 30, 2017, an increase of $2.9 million, or 61%, from revenues of $4.7 million for the three months ended September 30, 2016. The increase resulted primarily from an increase in the amount of drug substance sold to Pfizer, and drug product sold to Brazil.

Cost of Revenues

Cost of revenues was $6.1 million for the three months ended September 30, 2017, an increase of $1.8 million, or 43%, from cost of revenues of $4.2 million for the three months ended September 30, 2016. The increase resulted primarily from costs related to the production of drug substance for sale to Pfizer, and of drug product for sale to Brazil.

Research and Development Expenses, Net

Research and development expenses were $6.4 million for the three months ended September 30, 2017, an increase of $1.3 million, or 26%, from $5.1 million for the three months ended September 30, 2016. The increase resulted from the advancement of all of our pipeline programs in the clinical trial development plan.

We expect research and development expenses for our various development programs to continue to be our primary expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.8 million for the three months ended September 30, 2017, an increase of $0.8 million, or 41%, from $2.0 million for the three months ended September 30, 2016. The increase resulted primarily from an increase of $0.3 million in sales expenses.

Financial Expenses, net

Financial expenses, net was $3.7 million for the three months ended September 30, 2017, compared to financial expenses net of $0.6 million for the three months ended September 30, 2016. Financial expenses is comprised primarily from interest expense on convertible notes of $1.2 million for the period ended September 30, 2017. During the three months ended September 30, 2017, we recognized an extinguishment loss of $1.3 million due to convertible notes exchange.

Nine months ended September 30, 2017 compared to the nine months ended September 30, 2016

Revenues

We recorded revenues of $16.8 million during the nine months ended September 30, 2017, an increase of $9.7 million, or 136%, from revenues of $7.1 million for the nine months ended September 30, 2016. The increase resulted primarily from an increase in the amount of drug substance sold to Pfizer and drug products sold to Brazil.

Cost of Revenues

Cost of revenues was $13.7 million for the nine months ended September 30, 2017, an increase of $7.2 million, or 112%, from cost of revenues of $6.4 million for the nine months ended September 30, 2016. The increase resulted primarily from costs related to the production of drug substance for sale to Pfizer, and of drug product for sale to Brazil.

Research and Development Expenses, Net

Research and development expenses were $19.8 million for the nine months ended September 30, 2017, an increase of $0.9 million, or 5%, from $18.9 million for the nine months ended September 30, 2016.

We expect research and development expenses for our various development programs to continue to be our primary expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $8.2 million for the nine months ended September 30, 2017, an increase of $2.0 million, or 32%, from $6.2 million for the nine months ended September 30, 2016. The increase resulted primarily from an increase of $1.1 million in sales expenses.

Financial Expenses, net

Financial expenses net were $45.2 million for the nine months ended September 30, 2017, an increase of $43.1 million, compared to financial expenses net of $2.1 million for the nine months ended September 30, 2016. Financial expenses included a charge of $38.1 million as a result of the re-measurement of the fair value of the 7.5% convertible notes embedded derivative. In addition, financial expenses is comprised primarily from interest expense on convertible notes.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of significant revenue from sales of taliglucerase alfa, we have generated operating losses from our continuing operations since our inception. To date, we have funded our operations primarily with proceeds equal to $31.3 million from the sale of shares of convertible preferred and ordinary shares of Protalix Ltd., and an additional $14.1 million in connection with the exercise of warrants issued in connection with the sale of such shares, through December 31, 2008. In addition, on October 25, 2007, we generated gross proceeds of $50 million in connection with an underwritten public offering of our common stock and on each of March 23, 2011 and February 22, 2012, we generated gross proceeds of $22.0 million and $27.2 million, respectively, in connection with underwritten public offerings of our common stock.

In addition to the foregoing, on September 18, 2013, we completed a private placement of $69.0 million in aggregate principal amount of 4.50% convertible notes due 2018, including $9.0 million aggregate principal amount of the of 4.50% convertible notes related to the offering's initial purchaser's over-allotment option, which was exercised in full. In December 2016, we completed a private placement of $22.5 million in aggregate principal amount of 7.5% convertible notes due 2021. Finally, on July 25, 2017, we completed a private placement of an additional $10.0 million in aggregate principal amount of 7.5% convertible notes due 2021.

Pfizer paid Protalix Ltd. $60.0 million as an upfront payment in connection with the execution of the Pfizer Agreement and subsequently paid to Protalix Ltd. an additional $5.0 million upon Protalix Ltd.'s meeting a certain milestone. Protalix Ltd. also received a milestone payment of $25.0 million in connection with the FDA's approval of taliglucerase alfa in May 2012. Pfizer has also paid Protalix Ltd. $8.3 million in connection with the successful achievement of certain milestones under a clinical development agreement between Pfizer and Protalix Ltd. In connection with the execution of the Amended Pfizer Agreement, we received a $36.0 million payment from Pfizer, and Pfizer purchased 5,649,079 shares of our common stock for $10.0 million.

We believe that our existing cash and cash equivalents will be sufficient for at least 12 months. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Cash Flows

Net cash used in operations was $27.6 million for the nine months ended September 30, 2017. The net loss for the nine months ended September 30, 2017 of $70.1 million was partially offset by a change of $38.1 million in the fair value of convertible notes embedded derivative and increase of $8.7 million in accounts payable. Net cash used in investing activities for the nine months ended September 30, 2017 was $1.1 million and consisted primarily of purchases of property and equipment and an increase in restricted deposit. Net cash used in financing activities for the nine months ended September 30, 2017 was $1.4 million and consisted primarily of cash settlement of $11.0 million for certain conversions of our convertible notes which was partially offset by $9.5 million of net proceeds from the issuance of our 7.5% convertible notes.

Net cash used in operations was $24.7 million for the nine months ended September 30, 2016. The net loss for the nine months ended September 30, 2016 of $26.7 million was further increased by an increase of $1.4 million in accounts receivable, but was partially offset by depreciation expenses of $1.5 million and share based compensation of $765,000. Net cash used in investing activities for the nine months ended September 30, 2016 was approximately $725,000 and consisted primarily of purchases of property and equipment.

Future Funding Requirements

We expect to continue to incur significant expenditures in the near future, including significant research and development expenses related primarily to the clinical trials of pegunigalsidase alfa, alidornase alfa and OPRX-106, and the advancement of our other product candidates into anticipated later stage clinical trials.

Our future capital requirements will depend on many other factors, including our progress in commercializing Uplyso in Brazil, the progress and results of our clinical trials, the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates, conversions of our convertible notes from time to time, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

We may need to finance our future cash needs through corporate collaboration, licensing or similar arrangements, public or private equity offerings or debt financings. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. Any sale of additional equity or debt securities will likely result in dilution to our stockholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Effects of Inflation and Currency Fluctuations

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2017 and September 30, 2016.

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services. We do not believe currency fluctuations have had a material effect on our results of operations during the nine months ended September 30, 2017 and September 30, 2016.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2017 and September 30, 2016.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Currency Exchange Risk

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar. We consider the currency of the primary economic environment to be the currency in which we generate revenues and expend cash. Most of our revenues are denominated in U.S. dollars, approximately 50% of our expenses and capital expenditures are incurred in U.S. dollars, and a significant source of our financing has been provided in U.S. dollars. Since the dollar is the functional currency, monetary items maintained in currencies other than the dollar are remeasured using the rate of exchange in effect at the balance sheet dates and non-monetary items are remeasured at historical exchange rates. Revenue and expense items are remeasured at the average rate of exchange in effect during the period in which they occur. Foreign currency translation gains or losses are recognized in the statement of operations.

A portion of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A devaluation of 1% of the NIS will affect our income before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Nine months ended September 30,		Year ended December 31,
	2017	**2016**	**2016**
Average rate for period	3.629	3.844	3.841
Rate at period end	3.529	3.758	3.845

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS. These measures, however, may not adequately protect us from material adverse effects due to the impact of inflation in Israel.

Interest Rate Risk

Our exposure to market risk is confined to our cash and cash equivalents. We consider all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase, that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents. The primary objective of our investment activities is to preserve principal while maximizing the interest income we receive from our investments, without increasing risk. We invest any cash balances primarily in bank deposits and investment grade interest-bearing instruments. We are exposed to market risks resulting from changes in interest rates. We do not use derivative financial instruments to limit exposure to interest rate risk. Our interest gains may decline in the future as a result of changes in the financial markets.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The controls evaluation was conducted under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the Commission, and that material information relating to our company and our consolidated subsidiary is made known to management, including the Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in internal controls

There were no changes to our internal controls over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended September 30, 2017 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Unregistered Sales of Equity Securities

There were no unregistered sales of equity securities during the three months ended September 30, 2017.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Date	
3.1	Certificate of Incorporation of the Company	8-K	333-48677	3.1	April 1, 2016	
3.2	Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	July 1, 2016	
3.4	Bylaws of the Company	8-K	001-33357	3.2	April 1, 2016	
4.1	Form of Restricted Stock Agreement/Notice	8-K	001-33357	4.1	July 18, 2012	
4.2	Indenture, dated as of September 18, 2013, between Protalix BioTherapeutics, Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee	8-K	001-33357	4.1	September 18, 2013	
4.3	Form of 4.50% Convertible Note due 2018	8-K	001-33357	4.2	September 18, 2013	
4.4	Indenture, dated as of December 7, 2016, between Protalix BioTherapeutics, Inc. the guarantors party thereto, The Bank of New York Mellon Trust Company, N.A., as trustee and Wilmington Savings Fund Society, FSB, as collateral agent	8-K	001-33357	4.1	December 7, 2016	

4.5	Form of 7.50% Convertible Note due 2021 (Issued in 2016 Financing)	8-K	001-33357	4.2	December 7, 2016	
4.6	Form of 7.50% Convertible Note due 2021 (Issued in 2016 Exchange)	8-K	001-33357	4.3	December 7, 2016	
4.7	4.50% Notes Indenture, dated as of July 24, 2017, by and between Protalix BioTherapeutics, Inc. and The Bank of New York Mellon Trust Company, N.A., as trustee	8-K	001-33357	4.1	July 25, 2017	
4.8	First Supplemental Indenture, dated as of July 24, 2017, by and among Protalix BioTherapeutics, Inc., the guarantors party thereto, The Bank of New York Mellon Trust Company, N.A., as trustee, and Wilmington Savings Fund Society, FSB, as collateral agent	8-K	001-33357	4.2	July 25, 2017	
4.9	Form of 4.50% Note due 2022 (Issued in 2017 Exchange)	8-K	001-33357	4.4	July 25, 2017	
10.1	Note Purchase Agreement, dated of July 24, 2017, by and among Protalix BioTherapeutics, Inc. and the purchasers named therein	8-K	001-33357	10.1	July 25, 2017	
10.2	Exchange Agreement, dated of July 24, 2017, by and among Protalix BioTherapeutics, Inc. and the exchanging holders named therein	8-K	001-33357	10.2	July 25, 2017	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer					X

32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer	X
101.INS	XBRL INSTANCE FILE	X
101.SCH	XBRL SHEMA FILE	X
101.CAL	XBRL CALCULATION FILE	X
101.DEF	XBRL DEFINITION FILE	X
101.LAB	XBRL LABEL FILE	X
101.PRE	XBRL PRESENTATION FILE	X

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: November 8, 2017

By: /s/ Moshe Manor
Moshe Manor
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2017

By: /s/ Yossi Maimon
Yossi Maimon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, Moshe Manor, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protalix BioTherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

/s/ Moshe Manor
Moshe Manor
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Yossi Maimon, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protalix BioTherapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2017

/s/ Yossi Maimon
Yossi Maimon
Chief Financial Officer, Treasurer

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Moshe Manor, President and Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

Date: November 8, 2017

/s/ Moshe Manor
Moshe Manor
President and Chief Executive Officer

EXHIBIT 32.2

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Yossi Maimon, Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the dates and for the periods indicated.

This Certification has not been, and shall not be deemed, "filed" with the Securities and Exchange Commission.

Date: November 8, 2017

/s/ Yossi Maimon
Yossi Maimon
Vice President and Chief Financial Officer