Protalix BioTherapeutics, Inc.
Form 10-Q
May 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 March 31, 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)**

+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 May 1, 2018, approximately 145,569,955 shares of the Registrant’s common stock, $0.001 par value, were outstanding.

FORM 10-Q

TABLE OF CONTENTS

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;

- 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 4.50% convertible notes on or prior to June 16, 2018;

- 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)

	March 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,319	$ 51,163
Accounts receivable – Trade	4,756	1,721
Other assets	2,594	1,934
Inventories	7,019	7,833
Total current assets	$ 55,688	$ 62,651
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,798	1,887
PROPERTY AND EQUIPMENT, NET	7,311	7,676
Total assets	$ 64,797	$ 72,214
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,872	$ 7,521
Other	10,697	9,310
Convertible notes	5,930	5,921
Total current liabilities	$ 21,499	$ 22,752
LONG TERM LIABILITIES:		
Convertible notes	46,108	46,267
Deferred revenues	29,030	26,851
Liability for employee rights upon retirement	2,427	2,586
Other long term liabilities	5,172	5,051
Total long term liabilities	$ 82,737	$ 80,755
Total liabilities	$ 104,236	$ 103,507

COMMITMENTS		
CAPITAL DEFICIENCY	(39,439)	(31,293)
Total liabilities net of capital deficiency	$ 64,797	$ 72,214

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

1

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

	Three Months Ended	
	March 31, 2018	March 31, 2017
REVENUES	$4,553	$ 2,889
COST OF REVENUES	(2,924)	(2,088)
GROSS PROFIT	1,629	801
RESEARCH AND DEVELOPMENT EXPENSES (1)	(7,286)	(5,967)
Less – grants	843	1,338
RESEARCH AND DEVELOPMENT EXPENSES, NET	(6,443)	(4,629)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(2,498)	(2,537)
OPERATING LOSS	(7,312)	(6,365)
FINANCIAL EXPENSES	(2,220)	(2,087)
FINANCIAL INCOME	132	1,625
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES embedded derivative		(52,321)
FINANCIAL (EXPENSES) INCOME, NET	(2,088)	(52,783)
LOSS FOR THE PERIOD	(9,400)	(59,148)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$(0.06)	$ (0.48)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	145,305,982	124,467,602
(1) Includes share-based compensation	42	65
(2) Includes share-based compensation	20	53

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

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 three-month period ended March 31, 2017:					
Share-based compensation related to stock options			118		118
Convertible notes conversions	923,018	1	516		517
Net loss for the period				(59,148)	(59,148)
Balance at March 31, 2017	125,057,103	125	203,209	(271,804)	(68,470)
Balance at December 31, 2017	143,728,797	$144	$266,495	$ (297,932)	$(31,293)
Changes during the three-month period ended March 31, 2018:					
Share-based compensation related to stock options			46		46
Share-based compensation related to restricted stock award	29,898	*	16		16
Convertible notes conversions	1,811,260	2	1,190		1,192
Net loss for the period				(9,400)	(9,400)
Balance at March 31, 2018	145,569,955	$146	$267,747	$ (307,332)	$(39,439)

*Represents an amount less than $1.

(1)Common Stock, $0.001 par value; Authorized – as of March 31, 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)

	Three Months Ended	
	March 31, 2018	March 31, 2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (9,400)	$ (59,148)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	62	118
Depreciation	430	492
Financial (income) expenses, net (mainly exchange differences)	28	(9)
Changes in accrued liability for employee rights upon retirement	(124)	42
Gain on amounts funded in respect of employee rights upon retirement	(44)	(20)
Net loss (income) in connection with conversions of convertible notes	218	(1,445)
Change in fair value of convertible notes embedded derivative		52,321
Amortization of debt issuance costs and debt discount	619	590
Issuance of shares for interest payment in connection with conversions of convertible notes	205	
Changes in operating assets and liabilities:		
Increase in deferred revenues (including non-current portion)	2,179	1,088
Increase in accounts receivable and other assets	(3,512)	(3,092)
Decrease (increase) in inventories	814	(1,855)
Increase (decrease) in accounts payable and accruals	(1,009)	2,370
Increase in other long term liabilities	121	
Net cash used in continuing operations	(9,413)	(8,548)
Net cash provided by discontinued operations		122
Net cash used in operating activities	(9,413)	(8,426)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(249)	(220)
Increase in restricted deposit	(188)	(23)
Amounts funded in respect of employee rights upon retirement, net	109	(40)
Net cash used in investing activities	(328)	(283)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net payment for conversion of convertible notes		(6,726)
Net cash used in financing activities		(6,726)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(103)	171
NET DECREASE IN CASH AND CASH EQUIVALENTS	(9,844)	(15,264)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	51,163	63,281

BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$41,319	$ 48,017

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

	Three Months Ended	
	March 31, 2018	March 31, 2017
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 342	$ 636
Convertible notes conversions	$ 987	$ 517
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$ 145	$ 432

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

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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 alfataliglicerase 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 by Pfizer Inc. ("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 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 Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health (the "Brazilian MoH"), for taliglucerase alfa. Fiocruz's purchases of alfataliglicerase 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 Company is, at this time, continuing to supply alfataliglicerase to Fiocruz under the Brazil Agreement, and patients continue to be treated with alfataliglicerase in Brazil. Approximately 10% of adult Gaucher patients in Brazil are currently treated with alfataliglicerase. 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.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

In 2017, the Company received a purchase order from the Brazilian MoH for the purchase of alfataliglicerase for the treatment of Gaucher patients in Brazil for consideration of approximately $24.3 million. Shipments started in June 2017. The Company recorded revenues of $7.1 million for sales of alfataliglicerase to Fiocruz in 2017, and $2.6 million during the three months ended March 31, 2018.

On October 19, 2017, Protalix Ltd. and Chiesi Farmaceutici S.p.A. (“Chiesi”) entered into an Ex-US license (the “Chiesi Agreement”) pursuant to which Chiesi was granted an exclusive license for all markets outside of the United States to commercialize pegunigalsidase alfa. Under the terms and conditions of the Chiesi Agreement, Protalix Ltd. retained the right to commercialize pegunigalsidase in the United States.

Under the Chiesi Agreement, Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of the agreement and Protalix Ltd. is entitled to additional payments of up to $25.0 million in development costs, capped at $10.0 million per year. Protalix Ltd. is also eligible to receive additional payments of up to $320.0 million, in the aggregate, in regulatory and commercial milestone payments.

Under the terms of the Chiesi Agreement, Protalix Ltd. will manufacture all of the PRX-102 needed for all purposes under the agreement, subject to certain exceptions, and Chiesi will purchase pegunigalsidase alfa from Protalix, subject to certain terms and conditions. Chiesi will make tiered payments of 15% to 35% of its net sales, depending on the amount of annual sales, as consideration for the supply of pegunigalsidase alfa.

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 from the date of approval of the March 31, 2018 financial statements, 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, 2017, filed by the Company with the Commission. The comparative balance sheet at December 31, 2017 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.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

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

Diluted LPS is calculated in continuing operations. The calculation of diluted LPS does not include 78,142,133 and 73,800,491 shares of Common Stock underlying outstanding options and restricted shares of Common Stock and shares issuable upon conversion of outstanding convertible notes for the three months ended March 31, 2017 and 2018, respectively, because the effect would be anti-dilutive.

d. Revenue recognition

1. Revenues from supply agreements

The Company recognizes revenues from supply agreements and from selling products when control is transferred to the customer and collectability is probable.

2. Revenues from Chiesi Agreement

As Chiesi is obligated to acquire pegunigalsidase alfa from the Company and the development services are not considered distinct, development and manufacturing of a product to be commercialized by Chiesi is viewed as a single performance obligation. Since there is only one performance obligation, all payments received by Chiesi prior to the satisfaction of the Company's obligation will be deferred. Therefore, the $25.0 million upfront payment and future research and development reimbursement payments (up to $25.0 million) and any potential additional development milestone payments are contract liabilities and will be deferred until the commencement of commercial manufacturing.

e. Recently adopted standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance on revenues from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The

underlying principle is to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions require capitalization of certain contracts costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount timing and uncertainty of revenues and cash flows arising from an entity's contracts with customers. The guidance is effective for the interim and annual periods beginning on or after December 15, 2017. On January 1, 2018, the Company adopted the new accounting standard, ASC 606, Revenue from Contracts with Customers, and all the related amendments, using the modified retrospective method. The implementation of this Accounting Standards Update (ASU) did not have a material impact on the Company's consolidated financial statements.

In January 2016, the FASB issued ASU, No. 2016-01, Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities. The guidance affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. The guidance is effective for annual reporting periods beginning after December 15, 2017. The implementation of this ASU did not have a material impact on the Company's consolidated financial statements.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 2 – INVENTORIES

Inventory at March 31, 2018 and December 31, 2017 consisted of the following:

	March 31, 2018	December 31, 2017
	(U.S. dollars in thousands)	
Raw materials	$ 3,529	$ 3,838
Work in progress	317	485
Finished goods	3,173	3,510
Total inventory	$ 7,019	$ 7,833

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.

The fair value of the remaining $5.9 million in aggregate principal amount of the Company's outstanding 4.50% convertible promissory notes due 2018 (the "2013 Notes"), and of the remaining $58.1 million in aggregate principal amount of the Company's outstanding 7.50% secured convertible promissory notes due 2021 (the "2016 Notes"), is approximately $5.7 million and $69.3 million, respectively, based on a Level 3 measurement.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(Unaudited)

NOTE 3 – FAIR VALUE MEASUREMENT (continued)**:**

The Company prepared a valuation of the fair value of the 2013 Notes and the 2016 Notes (a Level 3 valuation) as of March 31, 2018. The values 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:

	2013 Notes	**2016 Notes**
Stock price (USD)	0.5399	0.5399
Expected term (years)	0.46	3.63
Risk free rate	1.88%	2.45%
Volatility	62.44%	70.96%
Yield	12.89%	12.44%

NOTE 4 – CONVERTIBLE NOTES

All of our outstanding convertible notes are accounted for using the guidance set forth in the FASB Accounting Standards Codification (ASC) 815 which requires 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 2013 Notes as a liability, on an aggregated basis, in their entirety. The 2016 Notes were accounted for partially as liability and equity components of the instrument and partially as a debt host contract with an embedded derivative resulting from the conversion feature. During the year ended December 31, 2017, the embedded derivative was reclassified to additional paid in capital.

Issuance costs regarding the issuance of the 2016 Notes are amortized using the effective interest rate.

The debt discount and debt issuance costs regarding the issuance of the 2013 Notes are deferred and amortized over the 2013 Notes period (5 years).

During the three months ended March 31, 2018, note holders converted $1.0 million aggregate principal amount of the 2016 Notes into a total of 1,338,707 shares of Common Stock, and cash payments of approximately $11,668, in the aggregate.

As of March 31, 2018, a total of $58.1 million aggregate principal amount of the 2016 Notes and $5.9 million aggregate principal amount of the 2013 Notes were outstanding.

NOTE 5 – REVENUES

The following table summarizes the Company’s disaggregation of revenues:

	March 31,	
(U.S. dollars in thousands)	2018	2017
Revenues:		
Pfizer	$1,980	$1,646
Brazil	$2,573	$1,243
	$4,553	$2,889

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, 2017. 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, 2017 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 including applying the unique properties of our ProCellEx system for the oral delivery of therapeutic proteins.

On October 19, 2017, Protalix Ltd., our wholly-owned subsidiary, and Chiesi entered into the Chiesi Agreement pursuant to which Chiesi was granted an exclusive license for all markets outside of the United States to commercialize pegunigalsidase alfa. Pegunigalsidase alfa is our chemically modified version of the recombinant protein alpha-Galactosidase-A protein that is currently being evaluated in phase III clinical trials for the treatment of Fabry disease. Under the terms and conditions of the Chiesi Agreement, Protalix Ltd. retained the right to commercialize pegunigalsidase alfa in the United States. Under the Chiesi Agreement, Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of the agreement and Protalix Ltd. is entitled to additional payments of up to $25.0 million in development costs, capped at $10.0 million per year. Protalix Ltd. is also eligible to receive an additional up to $320.0 million, in the aggregate, in regulatory and commercial milestone payments. Protalix Ltd. agreed to manufacture all of the PRX-102 needed for all purposes under the agreement, subject to certain exceptions, and Chiesi will purchase pegunigalsidase alfa from Protalix, subject to certain terms and conditions. Chiesi is required to make tiered payments of 15% to 35% of its net sales, depending on the amount of annual sales, as consideration for the supply of pegunigalsidase alfa.

In December 2017, the European Commission granted Orphan Drug Designation for pegunigalsidase alfa for the treatment of Fabry disease. The designation was granted after the European Medicine Agency's Committee for Orphan Medicinal Products, or the COMP, issued a positive opinion supporting the designation noting that we had established that there was medically plausible evidence that pegunigalsidase alfa will provide a significant benefit over existing approved therapies in the European Union for the treatment of Fabry disease. The COMP cited clinical and non-clinical justifications we provided to establish the significant benefit of pegunigalsidase alfa, noting that the COMP considered the justifications to constitute a clinically relevant advantage. Orphan Drug Designation for pegunigalsidase alfa qualifies Protalix Ltd. for access to a centralized marketing authorization procedure, including applications for inspections and for protocol assistance. If the orphan drug designation is maintained at the time pegunigalsidase alfa is approved for marketing in the European Union, if at all, we expect that PRX-102 will benefit from 10 years of market exclusivity within the European Union. The market exclusivity will not have any effect on Fabry disease treatments already approved at that time.

In January 2018, the FDA granted Fast Track designation to PRX-102. Fast Track designation is a process designed to facilitate the development and expedite the review of drugs and vaccines for serious conditions that fill an unmet medical need.

On May 1, 2012, the FDA approved for sale our first commercial product, taliglucerase alfa for injection, an 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 marketed under the name alfataliglicerase in Brazil and certain other Latin American countries, and under the name Elelyso in other territories.

Since its approval by the FDA, taliglucerase alfa has been marketed by Pfizer, as provided in the Pfizer Agreement. In October 2015, we entered into 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 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 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 alfataliglicerase to date have been significantly below certain agreed upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding, we are, at this time, continuing to supply alfataliglicerase to Fiocruz under the Brazil Agreement, and patients continue to be treated with alfataliglicerase 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 our best interest.

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 trial.

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

(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. We released final data generated in our phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis in March 2018.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Brazil), which we licensed to Pfizer, and the rights to pegunigalsidase alfa Chiesi 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 we filed our Annual Report on Form 10-K for the year ended December 31, 2017.

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 of our outstanding convertible notes are accounted for using the guidance set forth in FASB ASC 815 which requires 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 2013 Notes as a liability, on an aggregated basis, in their entirety. The 2016 Notes were accounted for partially as liability and equity components of the instrument and partially as a debt host contract with an embedded derivative resulting from the conversion feature. During the year ended December 31, 2017, the embedded derivative was reclassified to additional paid in capital.

Issuance costs regarding the issuance of the 2016 Notes are amortized using the effective interest rate.

The debt discount and debt issuance costs regarding the issuance of the 2013 Notes are deferred and amortized over the 2013 Notes period (5 years).

During the three months ended March 31, 2018, note holders converted $1.0 million aggregate principal amount of our 2016 Notes into a total of 1,338,707 shares of our common stock, and cash payments of approximately $11,668, in the aggregate.

As of March 31, 2018, a total of $58.1 million aggregate principal amount of the 2016 Notes and $5.9 million aggregate principal amount of the 2013 Notes were outstanding.

Results of Operations

Three months ended March 31, 2018 compared to the three months ended March 31, 2017

Revenues

We recorded revenues of $4.6 million during the three months ended March 31, 2018, an increase of $1.7 million, or 58%, compared to revenues of $2.9 million for the three months ended March 31, 2017. The increase resulted primarily from an increase of $1.3 million in drug product sold in Brazil.

Cost of Revenues

Cost of revenues was $2.9 million for the three months ended March 31, 2018, an increase of $836,000 from cost of revenues of $2.1 million for the three months ended March 31, 2017. The increase resulted primarily from increased sales in Brazil.

Research and Development Expenses, Net

Research and development expenses were $6.4 million for the three months ended March 31, 2018, an increase of $1.8 million, or 39%, compared to $4.6 million of research and development expenses for the three months ended March 31, 2017. The increase resulted primarily from an increase of $1.6 million in clinical trial related costs.

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 $2.5 million for the three months ended March 31, 2018 and for the three months ended March 31, 2017.

Financial Expenses, net

Financial expenses net were $2.1 million for the three months ended March 31, 2018 compared to financial expenses net of $52.8 million for the three months ended March 31, 2017. During the three months ended March 31, 2017, financial expenses included a charge of $52.3 million as a result of the re-measurement of the fair value of the 2016 Notes embedded derivative resulting mainly from the increase in the market value of our common stock during the three months ended March 31, 2017. In addition, financial expenses is composed primarily from interest expense on convertible notes of $1.2 million and $1.3 million for the three months ended March 31, 2018 and 2017, respectively.

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 incurred 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 $50.0 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 7.50% 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 7.50% 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 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 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.

In the fourth quarter of 2017, Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of the Chiesi Agreement.

Cash Flows

Net cash used in operations was $9.4 million for the three months ended March 31, 2018. The net loss for the three months ended March 31, 2018 of $9.4 million was further increased by a $3.5 million increase in accounts receivable and a decrease of $1.0 million in accounts payable, but was partially offset by an increase of $2.2 million in deferred revenues and by a decrease in inventories of $814,000. Net cash used in investing activities for the three months ended March 31, 2018 was $328,000 and consisted primarily of purchases of property and equipment, and an increase in restricted deposit.

Net cash used in operations was $8.4 million for the three months ended March 31, 2017. The net loss for the three months ended March 31, 2017 of $59.1 million was further increased by an increase of $3.1 million in accounts receivable and an increase of $1.9 million in inventories, but was partially offset by change of $52.3 million in the fair value of convertible notes embedded derivative and increase of $2.4 million in accounts payable. Net cash used in investing activities for the three months ended March 31, 2017 was $283,000 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. 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.

Our future capital requirements will depend on many other factors, including our progress in commercializing alfataliglicerase 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 outstanding 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, except with respect to the development-related payments and milestone payments that may become payable under the Chiesi Agreement. 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 three months ended March 31, 2018 and March 31, 2017.

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 three months ended March 31, 2018 and March 31, 2017.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of March 31, 2018 and March 31, 2017.

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:

	Three months ended March 31,		Year ended December 31,
	2018	2017	2017
Average rate for period	3.462	3.732	3.600
Rate at period end	3.514	3.632	3.467

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 March 31, 2018 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, 2017.

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 March 31, 2018.

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	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
4.8	Second Supplemental Indenture, dated as of November 27, 2017, by and among Protalix BioTherapeutics, Inc., the guarantors party hereto and The Bank of New York Mellon Trust Company, N.A., as trustee, registrar, paying agent and conversion agent	8-K	001-33357	4.1	December 1, 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: May 9, 2018 By: /s/ Moshe Manor
Moshe Manor
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 9, 2018 By: /s/ Yossi Maimon
Yossi Maimon
Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)