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, 2019

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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
common stock, $0.001 par value	PLX	NYSE American

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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	☐	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 May 1, 2019, approximately 148,382,299 shares of the Registrant's common stock, $0.001 par value, were outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth under the caption "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 the Company 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;

- the risk that the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or foreign regulatory authorities may not accept or approve a marketing application we file for any of our product candidates;

- our ability to remediate the material weakness in internal control over financial reporting and to maintain effective internal control over financial reporting;

- 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 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;

- risks related to our ability to maintain compliance with the continued listing standards of the NYSE American;

- 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 candidates 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 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 FDA, the EMA 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 numerous 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, 2018, 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)

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 30,363	$ 37,808
Accounts receivable – Trade	8,565	4,729
Other assets	1,706	1,877
Inventories	6,707	8,569
Total current assets	$ 47,341	$ 52,983
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	$ 1,801	$ 1,758
PROPERTY AND EQUIPMENT, NET	6,058	6,390
OPERATING LEASE RIGHT OF USE ASSETS	5,844	-
Total assets	$ 61,044	$ 61,131
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,870	$ 5,211
Other	10,480	10,274
Operating lease liabilities	1,257	
Contracts liability	9,429	9,868
Total current liabilities	$ 27,036	$ 25,353
LONG TERM LIABILITIES:		
Convertible notes	$ 48,670	$ 47,966
Contracts liability	32,979	33,027
Liability for employee rights upon retirement	2,426	2,374
Operating lease liabilities	4,498	
Other long term liabilities	5,290	5,292
Total long term liabilities	$ 93,863	$ 88,659
Total liabilities	$ 120,899	$ 114,012
COMMITMENTS		
CAPITAL DEFICIENCY	(59,855)	(52,881)
Total liabilities net of capital deficiency	$ 61,044	$ 61,131

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 per share data)
(Unaudited)

	Three Months Ended	
	March 31, 2019	**March 31, 2018**
REVENUES FROM SELLING GOODS	$ 3,530	$ 4,553
REVENUES FROM LICENSE AND R&D SERVICES	6,909	2,161
COST OF GOODS SOLD	(2,045)	(2,924)
RESEARCH AND DEVELOPMENT EXPENSES (1)	(11,701)	(7,286)
Less – grants	3	843
RESEARCH AND DEVELOPMENT EXPENSES, NET	(11,698)	(6,443)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(2,230)	(2,498)
OPERATING LOSS	(5,534)	(5,151)
FINANCIAL EXPENSES	(1,920)	(2,220)
FINANCIAL INCOME	190	132
FINANCIAL EXPENSES, NET	(1,730)	(2,088)
LOSS FOR THE PERIOD	$ (7,264)	$ (7,239)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.05)	$ (0.05)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	148,382,299	145,305,982
(1) Includes share-based compensation	$ 178	$ 42
(2) Includes share-based compensation	$ 112	$ 20

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)
(Unaudited)

	Common Stock (1)	Common Stock	Additional Paid–In Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
Balance at January 1, 2018	**143,728,797**	**$ 144**	**$ 266,495**	**$ (296,096)**	**$ (29,457)**
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				(7,239)	(7,239)
Balance at March 31, 2018	**145,569,955**	**$ 146**	**$ 267,747**	**$ (303,335)**	**$ (35,442)**
Balance at January 1, 2019	**148,382,299**	**$ 148**	**$ 269,524**	**$ (322,553)**	**$ (52,881)**
Changes during the three-month period ended March 31, 2019:					
Share-based compensation related to stock options			**290**		**290**
Net loss for the period				**(7,264)**	**(7,264)**
Balance at March 31, 2019	**148,382,299**	**$ 148**	**$ 269,814**	**$ (329,817)**	**$ (59,855)**

* Represents an amount less than $1.

(1) Common Stock, $0.001 par value; Authorized – as of March 31, 2019 and 2018 - 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, 2019	**March 31, 2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,264)	$ (7,239)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	290	62
Depreciation	405	430
Financial expenses, net (mainly exchange differences)	20	28
Changes in accrued liability for employee rights upon retirement	(24)	(124)
Gain on amounts funded in respect of employee rights upon retirement		(44)
Net loss in connection with conversions of convertible notes		218
Amortization of debt issuance costs and debt discount	704	619
Issuance of shares for interest payment in connection with conversions of convertible notes		205
Changes in operating assets and liabilities:		
Increase (decrease) in contracts liability (including non-current portion)	(487)	18
Increase in accounts receivable and other assets	(3,608)	(3,512)
Changes in right of use assets	(36)	
Decrease in inventories	1,862	814
Increase (decrease) in accounts payable and accruals	864	(1,009)
Increase (decrease) in other long term liabilities	(2)	121
Net cash used in operating activities	$ (7,276)	$ (9,413)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (170)	$ (249)
Increase in restricted deposit	(214)	(188)
Amounts funded in respect of employee rights upon retirement, net	13	109
Net cash used in investing activities	$ (371)	$ (328)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ 202	$ (103)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(7,445)	(9,844)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	37,808	51,163
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 30,363	$ 41,319

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, 2019	**March 31, 2018**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 128	$ 342
Convertible notes conversions		$ 987
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid		$ 145

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 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 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 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.

On October 19, 2017, Protalix Ltd. and Chiesi Farmaceutici S.p.A. ("Chiesi") entered into an Exclusive License and Supply Agreement (the "Chiesi Ex-US Agreement") pursuant to which Chiesi was granted an exclusive license for all markets outside of the United States to commercialize pegunigalsidase alfa. On July 23, 2018, Protalix Ltd. entered into an Exclusive License and Supply Agreement with Chiesi (the "Chiesi US Agreement") with respect to the commercialization of pegunigalsidase alfa in the United States.

Under each of the Chiesi Ex-US Agreement and the Chiesi US Agreement (collectively, the "Chiesi Agreements"), Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of the agreement. In addition, under the Chiesi Ex-US Agreement, Protalix Ltd. is entitled to additional payments of up to $25.0 million in pegunigalsidase alfa development costs, capped at $10.0 million per year, and to receive additional payments of up to $320.0 million, in the aggregate, in regulatory and commercial milestone payments. Under the Chiesi US Agreement, Protalix Ltd. is entitled to payments of up to a maximum of $20.0 million to cover development costs for pegunigalsidase alfa, subject to a maximum of $7.5 million per year, and to receive an additional up to a maximum of $760.0 million, in the aggregate, in regulatory and commercial milestone payments.

Under the terms of both of the Chiesi Agreements, Protalix Ltd. will manufacture all of the pegunigalsidase alfa needed under the agreements, subject to certain exceptions, and Chiesi will purchase pegunigalsidase alfa from Protalix, subject to certain terms and conditions. Under the Chiesi Ex-US Agreement, Chiesi is required to make tiered payments of 15% to 35% of its net sales, depending on the amount of annual sales outside of the United States, as consideration for product supply. Under the Chiesi US Agreement, Chiesi is required to make tiered payments of 15% to 40% of its net sales, depending on the amount of annual sales in the United States, as consideration for product supply.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

Since its approval by the FDA, taliglucerase alfa has been marketed by Pfizer in accordance with the exclusive license and supply agreement entered into between Protalix Ltd. and Pfizer, which is referred to herein as the Pfizer Agreement. In October 2015, the Company sold to Pfizer its share in the collaboration created under the Pfizer Agreement for the commercialization of Elelyso. 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 Fiocruz, an arm of 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 termination right, 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.

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 financial statements as of March 31, 2019, 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, 2018, filed by the Company with the Commission. The comparative balance sheet at December 31, 2018 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 73,800,491 and 78,202,020 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, 2018 and 2019, respectively, because the effect would be anti-dilutive.

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (continued):

d. Recently adopted standards

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). The new standard requires a lessee to record assets and liabilities on its balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the lessee's income statement. The Company adopted this standard as of January 1, 2019 on a modified retrospective basis and will not restate comparative periods. The Company will elect the package of practical expedients permitted under the transition guidance within the new standard which, among other things, allows the Company to carryforward the historical lease classification. The Company made an accounting policy election to keep leases with an initial term of 12 months or less off of its balance sheet. The Company recognized those lease payments in its statements of operations on a straight-line basis over the lease period.

As of the adoption date, the Company recognized an operating lease asset and liability of $5.9 million and $5.7 million, respectively, as of January 1, 2019 on its balance sheet.

e. Newly issued accounting pronouncements

In June 2018, the FASB issued ASU 2018-07, "Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-based Payment Accounting" that expands the scope of ASC Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should apply the requirements of ASC Topic 718 to nonemployee awards except for certain exemptions specified in ASU 2018-07. The guidance is effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company does not expect the adoption of ASU 2018-07 to have a material impact on its financial statements.

NOTE 2 - INVENTORIES

a. Inventories at March 31, 2019 and December 31, 2018 consisted of the following:

(*U.S. dollars in thousands*)	March 31, 2019	December 31, 2018
Raw materials	$ 3,047	$ 3,792
Work in progress	45	
Finished goods	3,615	4,777
Total inventory	$ 6,707	$ 8,569

b. During the year ended December 31, 2018 and the three months ended March 31, 2019, the Company recorded approximately $1.1 million and $65,000, respectively, for write-down of inventory under cost of goods sold.

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 $57.9 million principal amount of the Company's outstanding 7.50% convertible promissory notes due 2021 (the "2021 Notes") as of March 31, 2019 is approximately $64.5 million based on a Level 3 measurement.

The Company prepared a valuation of the fair value of the Company's outstanding 2021 Notes (a Level 3 valuation) as of March 31, 2019. The value of these notes was estimated by implementing the binomial model. The liability component was valued based on the Income Approach. The following parameters were used:

	2021 Notes
Stock price (USD)	0.44
Expected term	2.63
Risk free rate	2.21%
Volatility	81.56%
Yield	12.6%

NOTE 4 – OPERATING LEASES

The Company is a party to a number of lease agreements for its facilities, the latest of which has been extended until 2021. The Company has the option to extend certain of such agreements on two additional occasions for additional five-year periods each, for a total of 10 additional years. During the extended lease period, the aggregate monthly rental payments will increase by 7.5% - 10% for each option. The Company expects to exercise these options in future periods. As of March 31, 2019, the Company provided bank guarantees of approximately $412,000, in the aggregate, to secure the fulfillment of its obligations under the lease agreements. As of December 31, 2018, the future minimum lease payments required under the operating leases for such premises are approximately $758,000, $758,000 and $621,000, for fiscal years 2019 through 2021, respectively.

The Company entered into several three-year leases for vehicles which are regularly amended as new vehicles are leased. As of December 31, 2018, the future minimum lease payments for the years ending December 31, 2019, 2020 and 2021 are approximately $474,000, $333,000 and $82,000, respectively.

NOTE 4 – OPERATING LEASES (continued):

The following table sets forth data regarding the Company's operating leases for the three months ended March 31, 2019:

(*U.S. dollars in thousands)*	**March 31, 2019**
Operating lease costs	$ 292
Cash paid for amounts included in the measurement of lease liabilities	328
Right of use assets obtained in exchange for new operating lease liabilities	52
Weighted average remaining lease term (in years)	10.84
Weighted average discount rate	12.58%

The following table sets forth a maturity analysis of the Company's operating lease liabilities as of March 31, 2019:

(*U.S. dollars in thousands)*	**March 31, 2019**
2019 (excluding the three months ended March 31, 2019)	$ 947
2020	$ 1,135
2021	$ 888
2022	$ 774
2023	$ 770
After 2024	$ 6,380
Total undiscounted cash flows	$ 10,894
Less: imputed interest	$ 5,139
Present value of lease liabilities	$ 5,755

NOTE 5 – REVENUES

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

	Three months ended March 31,	
(U.S. dollars in thousands)	**2019**	**2018**
Pfizer	$ 1,356	$ 1,980
Brazil	$ 2,174	$ 2,573
Total revenues from selling goods	**$ 3,530**	**$ 4,553**
Revenues from license and R&D services	**$ 6,909**	**$ 2,161**

The following table sets forth data regarding the Company's contract liability:

	Three months ended March 31,	
(U.S. dollars in thousands)	**2019**	**2018**
Contract liabilities at the beginning of the period	$ 42,895	$ 25,015
Additions during the period	6,422	2,179
Revenue recognized during the period	(6,909)	(2,161)
Contract liabilities at the end of the period	$ 42,408	$ 25,033

The following table represents the Company's unsatisfied performance obligation:

	March 31,	
(U.S. dollars in thousands)	**2019**	**2018**
Unsatisfied performance obligation	$ 64,581	$ 91,033

NOTE 6 – SUBSEQUENT EVENTS

The Company has evaluated subsequent events through the date on which the consolidated financial statements were available to be issued and no subsequent events were identified.

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, 2018. 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, 2018 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 Ex-US 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 Ex-US Agreement, Protalix Ltd. retained the right to commercialize pegunigalsidase alfa in the United States. Under the Chiesi Ex-US 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 in the aggregate, capped at $10.0 million per year. Protalix Ltd. is also eligible to receive an additional up to a maximum of $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.

On July 23, 2018, Protalix Ltd. entered into the Chiesi US Agreement with respect to the development and commercialization of pegunigalsidase alfa in the United States. Under the terms of the Chiesi US Agreement, Protalix Ltd. granted to Chiesi exclusive licensing rights for the commercialization of PRX-102 in the United States. Protalix Ltd. is entitled to an upfront, non-refundable, non-creditable payment of $25.0 million from Chiesi and additional payments of up to a maximum of $20.0 million, in the aggregate, to cover development costs for PRX-102, subject to a maximum of $7.5 million per year. Protalix Ltd. is also eligible to receive an additional up to a maximum of $760.0 million, in the aggregate, in regulatory and commercial milestone payments. Chiesi will also make tiered payments of 15% to 40% of its net sales under the Chiesi US Agreement to Protalix Ltd., depending on the amount of annual sales, subject to certain terms and conditions, as consideration for product supply.

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. 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. 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 our termination right, 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 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. Additional data was released in June 2018.

We have licensed the rights to commercialize taliglucerase alfa worldwide (other than Brazil) to Pfizer, and the rights to commercialize pegunigalsidase alfa worldwide to Chiesi. Otherwise, we hold the worldwide commercialization rights to our other 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 been no material changes to our critical accounting policies since we filed our Annual Report on Form 10-K for the year ended December 31, 2018.

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.

Results of Operations

Three months ended March 31, 2019 compared to the three months ended March 31, 2018

Revenues from Selling Goods

We recorded revenues from selling goods of $3.5 million during the three months ended March 31, 2019, a decrease of $1.0 million, or 22%, compared to revenues of $4.6 million for the three months ended March 31, 2018. The decrease resulted primarily from a decrease of $0.6 million in sales of drug substance to Pfizer.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $6.9 million for the three months ended March 31, 2019, an increase of $4.7 million compared to revenues of $2.2 million for the three months ended March 31, 2018. Revenues from the license agreements represent the revenues we recognized in connection with the Chiesi Agreements.

Cost of Goods Sold

Cost of goods sold was $2.0 million for the three months ended March 31, 2019, a decrease of $0.9 million, or 30%, from cost of goods sold of $2.9 million for the three months ended March 31, 2018. The decrease is mainly due to a decrease in selling goods.

Research and Development Expenses, Net

Research and development expenses were $11.7 million for the three months ended March 31, 2019, an increase of $5.3 million, or 82%, compared to $6.4 million of research and development expenses for the three months ended March 31, 2018. The increase resulted primarily from an increase of $3.0 million in clinical trial related costs.

We expect research and development expenses to continue to be our primary expense as we enter into a more advanced stage of preclinical and clinical trials for certain of our product candidates, primarily with respect to pegunigalsidase alfa.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.2 million for the three months ended March 31, 2019, a decrease of $0.3 million, or 11%, compared to $2.5 million for the three months ended March 31, 2018.

Financial Expenses, net

Financial expenses net were $1.7 million for the three months ended March 31, 2019, a decrease of $0.4 million, or 17%, compared to financial expenses net of $2.1 million for the three months ended March 31, 2018. Financial expenses are comprised primarily from interest expense on outstanding convertible notes of $1.1 million and $1.2 million for the three months ended March 31, 2019 and 2018, 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 generated operating losses from our continuing operations since our inception. To date, we have funded our operations primarily with net 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. We believe that the funds currently available to us are sufficient to satisfy our capital needs for at least 12 months.

In addition to the foregoing, on September 18, 2013, we completed a private placement of $69.0 million in aggregate principal amount of our 2018 Notes, including $9.0 million aggregate principal amount of 2018 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 2021 Notes. Finally, on July 25, 2017, we completed a private placement of an additional $10.0 million in aggregate principal amount of 2021 Notes.

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.

In the fourth quarter of 2017, Chiesi made a payment to Protalix Ltd. of $25.0 million in connection with the execution of the Chiesi Ex-US Agreement and in the third quarter of 2018, Chiesi made a payment to Protalix Ltd. of $25.0 million in connection with the execution of the Chiesi US Agreement.

Cash Flows

Net cash used in operations was $7.3 million for the three months ended March 31, 2019. The net loss for the three months ended March 31, 2019 of $7.3 million was further increased by a $3.6 million increase in accounts receivable, but was partially offset by an increase of $0.9 million in accounts payable and accruals and by a decrease in inventories of $1.9 million. Net cash used in investing activities for the three months ended March 31, 2019 was $0.4 million and consisted primarily of purchases of property and equipment, and an increase in restricted deposit.

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 $7.2 million was further increased by a $3.5 million increase in accounts receivable, and a decrease of $1.0 million in accounts payable and accruals, but was partially offset 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.

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 PRX-102. We believe that our existing cash and cash equivalents and commitments 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, particularly our clinical trials of pegunigalsidase alfa, the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates, conversions of our 2021 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 and/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 Agreements. 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, 2019 and March 31, 2018.

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, 2019 and March 31, 2018.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of March 31, 2019 and March 31, 2018.

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,
	2019	2018	2018
Average rate for period	3.644	3.462	3.595
Rate at period end	3.632	3.514	3.748

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.

The evaluation of our disclosure controls and procedures included a review of the controls' objectives and design, our implementation of the controls and their effect on the information generated for use in this Quarterly Report on Form 10-Q. This type of evaluation will be performed on a quarterly basis so that the conclusions of management, including the Chief Executive Officer and Chief Financial Officer, concerning the effectiveness of the disclosure controls and procedures can be reported in our periodic reports on Forms 10-Q and Forms 10-K. The overall goals of these various evaluation activities are to monitor our disclosure controls and procedures, and to modify them as necessary. Our intent is to maintain the disclosure controls and procedures as dynamic systems that change as conditions warrant.

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 not effective as of March 31, 2019 due to the material weakness in internal control over financial reporting described below.

Our Chief Executive Officer and Chief Financial Officer have concluded that notwithstanding the existence of the material weakness, the consolidated financial statements included in this Quarterly Report on Form 10-Q present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles. Additional corrective actions continue to address the internal control material weakness as described below under the section "Remediation Plan."

Material Weakness in Internal Control over Financial Reporting

Management has concluded that our internal control over financial reporting was not effective as of the end of our last fiscal quarter to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles. We determined that a material weakness in our internal control over financial reporting existed as of March 31, 2019 in that we did not maintain effective internal controls related to accounting for complex revenue contracts. Specifically, we did not properly assess the performance obligations we had with regard to certain out-licensing arrangements which became material to our company during 2018. We reviewed the results of management's assessment with the Audit Committee of our Board of Directors.

Remediation Plan

In response to the identified material weakness, our management, with the oversight of the Audit Committee of the Board of Directors, has updated our revenue recognition processes and controls with respect to out-licensing arrangements, and retained a globally recognized business and accounting advisory firm to assist us in improving our internal processes in connection with revenue recognition. While certain remedial actions have been completed in the first quarter of 2019, we intend to continue to update our revenue recognition processes and controls and to implement additional control procedures as the need to do so is identified by our management. The remediation efforts are intended both to address the identified material weakness and to enhance our overall financial control environment.

The material weakness will not be considered remediated until our management designs and implements effective controls that operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. We will monitor the effectiveness of our remediation plan and will refine its remediation plan as appropriated.

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 Control over Financial Reporting

Except with respect to the new lease accounting standard, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended March 31, 2019 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, 2018.

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

There were no unregistered sales of equity securities during the three months ended March 31, 2019.

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 or Furnished 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	
3.3	Second Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	October 17, 2018	
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 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	
4.3	Form of 7.50% Convertible Note due 2021 (Issued in 2016 Financing)	8-K	001-33357	4.2	December 7, 2016	
4.4	Form of 7.50% Convertible Note due 2021 (Issued in 2016 Exchange)	8-K	001-33357	4.3	December 7, 2016	
4.5	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	
4.6	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 SCHEMA 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 6, 2019

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

Date: May 6, 2019

By: /s/ Yossi Maimon
Yossi Maimon
Vice President and 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: May 6, 2019

/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: May 6, 2019

/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 March 31, 2019 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: May 6, 2019

/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 March 31, 2019 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: May 6, 2019

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