UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 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 November 1, 2019, approximately 148,382,299 shares of the Registrant's common stock, $0.001 par value, were outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 21,442	$ 37,808
Accounts receivable – Trade	8,716	4,729
Other assets	2,756	1,877
Inventories	7,525	8,569
Total current assets	$ 40,439	$ 52,983
NON-CURRENT ASSETS:		
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	$ 1,953	$ 1,758
PROPERTY AND EQUIPMENT, NET	5,573	6,390
OPERATING LEASE RIGHT OF USE ASSETS	5,764	-
Total assets	$ 53,729	$ 61,131
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 7,755	$ 5,211
Other	12,730	10,274
Operating lease liabilities	1,222	-
Contracts liability	11,612	9,868
Total current liabilities	$ 33,319	$ 25,353
LONG TERM LIABILITIES:		
Convertible notes	$ 50,163	$ 47,966
Contracts liability	28,586	33,027
Liability for employee rights upon retirement	2,606	2,374
Operating lease liabilities	4,532	-
Other long term liabilities	5,372	5,292
Total long term liabilities	$ 91,259	$ 88,659
Total liabilities	$ 124,578	$ 114,012
COMMITMENTS		
CAPITAL DEFICIENCY	$ (70,849)	$ (52,881)
Total liabilities net of capital deficiency	$ 53,729	$ 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)

	Nine Months Ended		Three Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
REVENUES FROM SELLING GOODS	$ 12,086	$ 7,222	$ 5,126	$ 663
REVENUES FROM LICENSE AND R&D SERVICES	24,848	16,665	9,122	11,672
COST OF GOODS SOLD	(7,945)	(7,024)	(3,205)	(1,917)
RESEARCH AND DEVELOPMENT EXPENSES, NET(1)	(35,021)	(23,755)	(10,000)	(10,071)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(6,885)	(8,744)	(2,587)	(4,088)
OPERATING LOSS	(12,917)	(15,636)	(1,544)	(3,741)
FINANCIAL EXPENSES	(5,877)	(5,824)	(2,050)	(1,811)
FINANCIAL INCOME	227	437	34	230
FINANCIAL EXPENSES, NET	(5,650)	(5,387)	(2,016)	(1,581)
NET LOSS FOR THE PERIOD	$ (18,567)	$ (21,023)	$ (3,560)	$ (5,322)
NET LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED	$ (0.13)	$ (0.14)	$ (0.02)	$ (0.04)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	148,382,299	146,752,355	148,382,299	148,187,513
(1) Includes share-based compensation	$ 426	$ 54	$ 110	$ (14)
Includes grants	$ (55)	$ (1,810)	$ (52)	$ (732)
(2) Includes share-based compensation	$ 173	$ 42	$ 86	$ 8

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 per share data)
(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 nine-month period ended September 30, 2018:					
Share-based compensation related to stock options			80		80
Share-based compensation related to restricted stock award	29,898	*	16		16
Convertible notes conversions	1,928,907	2	1,289		1,291
Convertible notes exchange	2,613,636	2	1,148		1,150
Net loss for the period				(21,023)	(21,023)
Balance at September 30, 2018	**148,301,238**	**$ 148**	**$ 269,028**	**$ (317,119)**	**$ (47,943)**
Balance at January 1, 2019	**148,382,299**	**$ 148**	**$ 269,524**	**$ (322,553)**	**$ (52,881)**
Changes during the nine-month period ended September 30, 2019:					
Share-based compensation related to stock options			599		599
Net loss for the period				(18,567)	(18,567)
Balance at September 30, 2019	**148,382,299**	**$ 148**	**$ 270,123**	**$ (341,120)**	**$ (70,849)**
Balance at June 30, 2018	**148,183,591**	**$ 148**	**$ 268,907**	**$ (311,797)**	**$ (42,742)**
Changes during the three-month period ended September 30, 2018:					
Share-based compensation related to stock options			22		22
Convertible notes conversions	117,647		99		99
Net loss for the period				(5,322)	(5,322)
Balance at September 30, 2018	**148,301,238**	**$ 148**	**$ 269,028**	**$ (317,119)**	**$ (47,943)**
Balance at June 30, 2019	**148,382,299**	**$ 148**	**$ 269,927**	**$ (337,560)**	**$ (67,485)**
Changes during the three-month period ended September 30, 2019:					
Share-based compensation related to stock options			196		196
Net loss for the period				(3,560)	(3,560)
Balance at September 30, 2019	**148,382,299**	**$ 148**	**$ 270,123**	**$ (341,120)**	**$ (70,849)**

* Represents an amount less than $1.

(1) Common Stock, $0.001 par value; Authorized – as of September 30, 2019 and 2018 - 350,000,000 and 250,000,000, respectively.

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

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

	Nine Months Ended	
	September 30, 2019	**September 30, 2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (18,567)	$ (21,023)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	599	96
Depreciation	1,205	1,257
Financial expenses (income), net (mainly exchange differences)	371	(37)
Changes in accrued liability for employee rights upon retirement	51	(86)
Gain on amounts funded in respect of employee rights upon retirement		(45)
Net loss in connection with conversions of convertible notes		204
Amortization of debt issuance costs and debt discount	2,197	1,916
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)	(2,697)	18,264
Increase in accounts receivable and other assets	(4,767)	(3,661)
Changes in right of use assets	(92)	
Decrease (increase) in inventories	1,044	(126)
Increase (decrease) in accounts payable and accruals	4,905	(1,805)
Increase in other long term liabilities	80	1,103
Net cash used in operating activities	$ (15,671)	$ (3,738)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (599)	$ (498)
Increase in restricted deposit	(254)	(247)
Amounts funded in respect of employee rights upon retirement, net	(59)	70
Net cash used in investing activities	$ (912)	$ (675)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net payment for convertible notes		$ (4,752)
Net cash used in financing activities		(4,752)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ 217	$ (130)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(16,366)	(9,295)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	37,808	51,163
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 21,442	$ 41,868

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

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

(Continued) - 2

	Nine Months Ended	
	September 30, 2019	**September 30, 2018**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 14	$ 237
Convertible notes conversions		$ 2,236
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$ 2,172	$ 2,411

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; 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.

The Company, together with its commercialization partner for PRX-102, Chiesi Farmaceutici S.p.A. ("Chiesi"), plans to file a biologics license application ("BLA") for PRX-102 for the treatment of Fabry disease by April 2020 through the Accelerated Approval pathway of the U.S. Food and Drug Administration ("FDA"). This decision is the result of a series of meetings and correspondence between the Company and Chiesi, on the one hand, and the FDA, on the other hand. The Company and Chiesi have initiated preparations for the BLA submission based on clinical data generated in the one-year completed phase I/II clinical trials of PRX-102 and from the ongoing phase III BRIDGE clinical trial, as well as safety data from all on-going studies. The BLA will also include extensive data from the Company's completed nonclinical program, as well as information regarding production of PRX-102.

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 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 each 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.

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

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.

Since its approval by the FDA, taliglucerase alfa has been marketed by Pfizer Inc. ("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, Protalix Ltd. and Pfizer entered into an amended exclusive license and supply agreement, which is referred to herein as the Amended Pfizer Agreement, pursuant to which 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 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 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.

Going Concern

Since the Company is engaged in research and development activities, it has not derived significant income from its activities and has incurred accumulated losses in the amount of $341.0 million through September 30, 2019 and cash outflows from operating activities. As of September 30, 2019, the Company has outstanding $57.9 million aggregate principal amount of its 7.50% convertible promissory notes due 2021 (the "2021 Notes") which are secured with a perfected lien on all of the Company's assets. Under the terms of the indenture governing the 2021 Notes, the Company is required to maintain a minimum cash balance of at least $7.5 million. As of September 30, 2019, the Company had cash and cash equivalents of $21.4 million. Based on its current cash resources and commitments, the Company may not be able to meet its current planned development activities and the corresponding level of expenditures for the next 12 months from the date of approval of the financial statements as of September 30, 2019 absent a refinancing or restructuring. These factors raise substantial doubt as to the Company's ability to continue as a going concern.

The Company's management is in the process of evaluating refinancing and restructuring alternatives, including a restructuring of its outstanding convertible notes, and related transactions. However, there is no certainty about the Company's ability to obtain such funding.

The financial information has been prepared on a going concern basis, which assumes the Company will continue to realize its assets and discharge its liabilities in the normal course of business. If the Company does not complete a refinancing or restructuring, it will need to curtail or cease operations. These financial statements do not include any adjustments that may be necessary should the Company be unable to continue as a going concern.

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

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 U.S Securities and Exchange Commission (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.

The calculation of diluted LPS does not include 73,310,911 and 78,269,464 shares of Common Stock underlying outstanding options and restricted shares of Common Stock and shares issuable upon conversion of outstanding convertible notes for the nine months ended September 30, 2018 and 2019, respectively, and 73,280,977 and 78,547,287 shares of Common Stock for the three months ended September 30, 2018 and 2019, respectively, because the effect would be anti-dilutive.

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 elected 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.

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

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 September 30, 2019 and December 31, 2018 consisted of the following:

(*U.S. dollars in thousands)*	**September 30, 2019**	**December 31, 2018**
Raw materials	$ 3,691	$ 3,792
Work in progress	233	-
Finished goods	3,601	4,777
Total inventory	$ 7,525	$ 8,569

b. During the year ended December 31, 2018 and the nine months ended September 30, 2019, the Company recorded approximately $1.1 million and $29,000, 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.

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

The fair value of the $57.9 million aggregate principal amount of the Company's outstanding 2021 Notes as of September 30, 2019 is approximately $57.7 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 September 30, 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)	0.21
Expected term	2.13
Risk free rate	1.62%
Volatility	74.99%
Yield	10.53%

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 the end of 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 September 30, 2019, the Company provided bank guarantees of approximately $437,000 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.

The following table sets forth data regarding the Company's operating leases for the nine and three months ended September 30, 2019:

	Nine Months Ended	**Three Months Ended**
(*U.S. dollars in thousands)*	**September 30, 2019**	
Operating lease costs	$ 907	$ 314
Cash paid for amounts included in the measurement of lease liabilities	999	337
Right of use assets obtained in exchange for new operating lease liabilities	282	55

The following table sets forth data regarding the Company's operating leases as of September 30, 2019:

	September 30, 2019
Weighted average remaining lease term (in years)	10.6
Weighted average discount rate	12.55%

NOTE 4 - OPERATING LEASES (continued)**:**

The following table sets forth a maturity analysis of the Company's operating lease liabilities as of September 30, 2019:

(*U.S. dollars in thousands*)	September 30, 2019
2019 (excluding the nine months ended September 30, 2019)	$ 300
2020	$ 1,128
2021	$ 949
2022	$ 826
2023	$ 803
After 2023	$ 6,656
Total undiscounted cash flows	$ 10,662
Less: imputed interest	$ 4,908
Present value of operating lease liabilities	$ 5,754

NOTE 5 – REVENUES

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

	Nine Months Ended September 30,	
	2019	**2018**
(U.S. dollars in thousands)		
Pfizer	$ 4,701	$ 4,649
Brazil	$ 7,385	$ 2,573
Total revenues from selling goods	$ 12,086	$ 7,222
Revenues from license and R&D services	$ 24,848	$ 16,665

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

	Nine Months Ended September 30,	
(U.S. dollars in thousands)	**2019**	**2018**
Contracts liability at the beginning of the period	$ 42,895	$ 25,015
Additions during the period	22,151	34,929
Revenue recognized during the period	(24,848)	(16,665)
Contracts liability at the end of the period	$ 40,198	$ 43,279

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

	September 30,	
(U.S. dollars in thousands)	**2019**	**2018**
Unsatisfied performance obligation	$ 50,584	$ 76,969

NOTE 6 - STOCK TRANSACTIONS

In September 2019, the Company granted to its new chief financial officer 10-year options to purchase, in the aggregate, 800,000 shares of Common Stock under the Company's 2006 Employee Stock Incentive Plan, as amended (the "Plan"). The options have an exercise price equal to $0.2 per share and vest over a four-year period in 16 equal quarterly increments. Vesting of the options is subject to acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan, and are subject to certain other terms and conditions. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $97,000 based on the following weighted average assumptions: share price equal to $0.2; dividend yield of 0% for all years; expected volatility of 66.48%; risk-free interest rates of 1.695%; and expected life of six years.

NOTE 7 – SUBSEQUENT EVENTS

On October 16, 2019, the Company received total proceeds of approximately $2.6 million from expense reimbursements in relation to its collaboration with Chiesi and on October 18, 2019, the Company received total proceeds of approximately $3.2 million from sales of alfataliglicerase to Fiocruz.

In accordance with ASC 855 "Subsequent Events" the Company evaluated subsequent events through the date the condensed consolidated financial statements were issued. The Company concluded that no other subsequent events have occurred that would require recognition or disclosure in the condensed consolidated financial statements.

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 within the meanings of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to our company or our 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 as a result of several factors including those set forth under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.

Examples of the risks and uncertainties include, but are not limited to, the following:

- the risk that the FDA will not accept an application for Accelerated Approval of PRX-102 with the data generated to date or will request additional data or other conditions of our submission, or that the FDA, the European Medicines Agency, or the EMA, or other foreign regulatory authorities may not accept or approve a marketing application we file for any of our other product candidates;

- risks related to our ability to identify and complete strategic alternatives on attractive terms or at all within the time period required to regain compliance with the continued listing standards of the NYSE American LLC, or the NYSE American, or to otherwise maintain compliance with its continued listing standards;

- risks related to our ability to continue as a going concern absent a strategic transaction, refinancing or restructuring;

- the risk that the results of our clinical trials will not support the applicable claims of 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 our collaborators, distributors or partners;

- risks relating to our ability to make required payments under our outstanding convertible notes or any other indebtedness;

- our dependence on performance by third-party providers of services and supplies;

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

- risks related to our supply of drug product to Pfizer;

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

· potential product liability risks, and risks of securing adequate levels of related insurance coverage; and

· the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties.

Company Overview

· Protalix BioTherapeutics, Inc. is a biopharmaceutical company focused on the development, production and commercialization of improved recombinant therapeutic proteins produced by its proprietary ProCellEx® plant cell-based protein expression system.

· We have recently undertaken many key transformational steps to strengthen the company and position our company to reemerge as a leading Israeli pharmaceutical company including the appointment of Dror Bashan as President and Chief Executive Officer and Eyal Rubin as Sr. Vice President and Chief Financial Officer. In addition, in August 2019, Zeev Bronfeld, a long-time member of our Board of Directors and successful life sciences executive and investor, was elected as the new Chairman of the Board.

· Our new management team has laid out the following key objectives for 2019-2021: improving our capital structure, pursuing strategic partnerships and alliances, actively moving our pipeline towards commercialization and performing a strategic and scientific review of our technology and assets with the goal of forming a research and development plan.

· Elelyso® (taliglucerase alfa), our first commercial product for the treatment of Gaucher disease, was the first plant cell derived recombinant protein therapeutic approved by major regulatory authorities, including the FDA and the EMA.

· Pegunigalsidase alfa (PRX-102), our most advanced pipeline drug candidate, is produced through our ProCellEx technology and is under development as a treatment for Fabry disease. We are currently running three phase III clinical trials and we, together with Chiesi, plan the submission of a BLA for PRX-102 via the FDA's Accelerated Approval pathway by April 2020.

Recent Developments

· On July 29, 2019, we appointed Eyal Rubin as our Senior Vice President and Chief Financial Officer, effective September 22, 2019. Mr. Rubin is an experienced healthcare finance professional with over 20 years of diverse leadership experience including his most recent role as Executive Vice President and Chief Financial Officer of BrainStorm Cell Therapeutics, Inc., a publicly traded biotechnology company.

· On August 13, 2019, we announced that our Board of Directors unanimously elected Zeev Bronfeld, a current independent director, as Chairman of the Board. Mr. Bronfeld is one of the earliest investors in our company and has deep experience in the management of biotechnology and life science companies.

· On August 22, 2019, we announced that we have engaged a first-tier financial advisory firm to assist us in evaluating and pursuing strategic alternatives to maximize stakeholder value through financings and partnerships.

· On August 30, 2019, we announced that we received a deficiency letter from NYSE American LLC stating that we are not in compliance with the continued listing standards as set forth in Section 1003(a)(i)-(iii) of the NYSE American Company Guide as we have reported a stockholders' equity deficiency as of June 30, 2019 and net losses in our five most recent fiscal years ended December 31, 2018. The letter has no immediate effect on the listing of our common stock on the NYSE American. Subsequently, in accordance with the NYSE American Company Guide, we submitted to the NYSE American a plan to regain compliance with the continued listing standards.

· On September 24, 2019, we and Chiesi announced the completion of enrollment in the BALANCE study, one of our three Phase III clinical trials of PRX-102 for the treatment of Fabry disease. The head-to-head Phase III BALANCE clinical study is designed to evaluate the safety and efficacy of PRX-102 compared to agalsidase beta (Fabrazyme®) on renal function in Fabry patients with progressing kidney disease previously treated with agalsidase beta. To date, more than 66 patients are being treated in our various extension studies after opting to continue treatment with PRX-102 after completion of an original study.

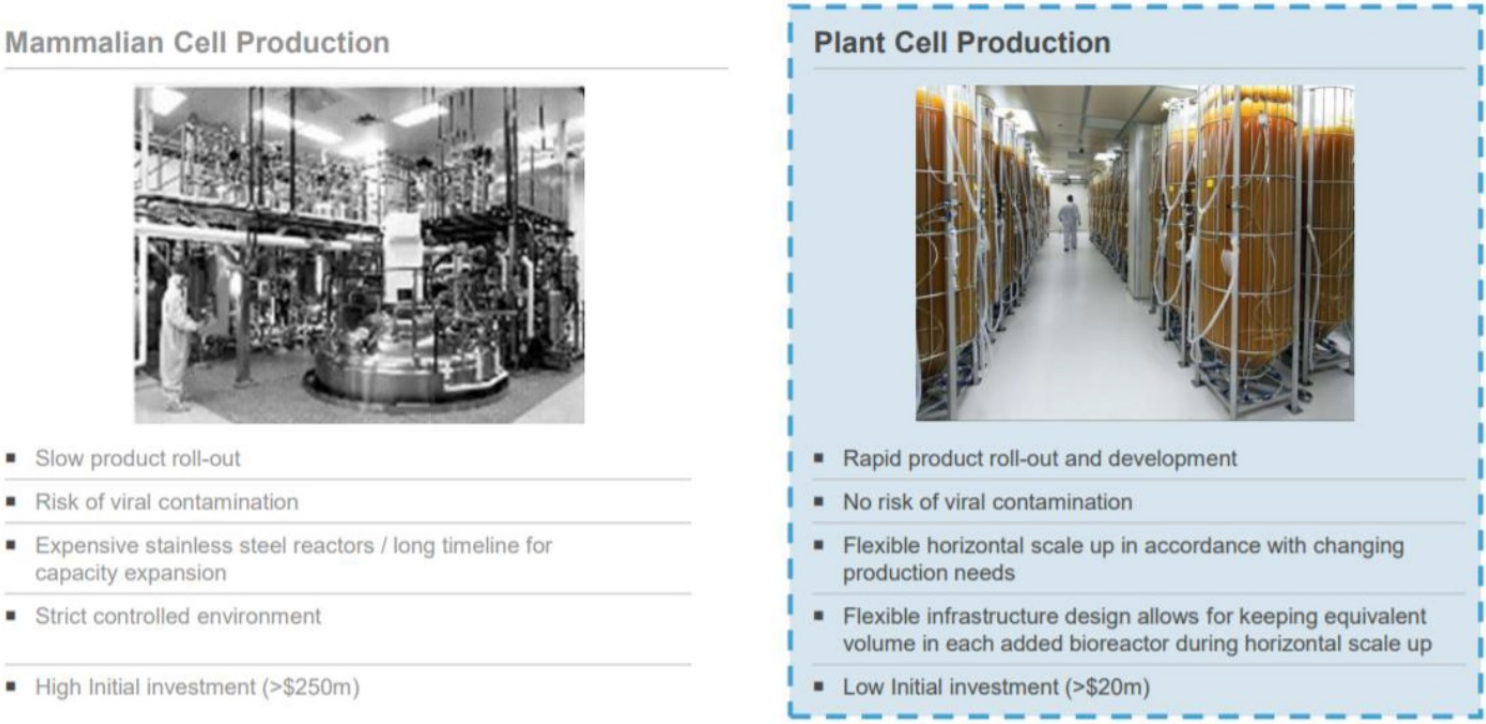
· On October 17, 2019, we announced positive 12-month interim data from the first 16 out of the 22 adult patients (9 males and 7 females) enrolled in the BRIDGE Phase III open label switch-over study of PRX-102 for the treatment of Fabry disease. The 12 months on-treatment interim data demonstrate a mean improvement in kidney function, in both male and female patients, when switched from agalsidase alfa (Replagal®) to PRX-102, and will help to support the expected FDA BLA filing under Accelerated Approval.

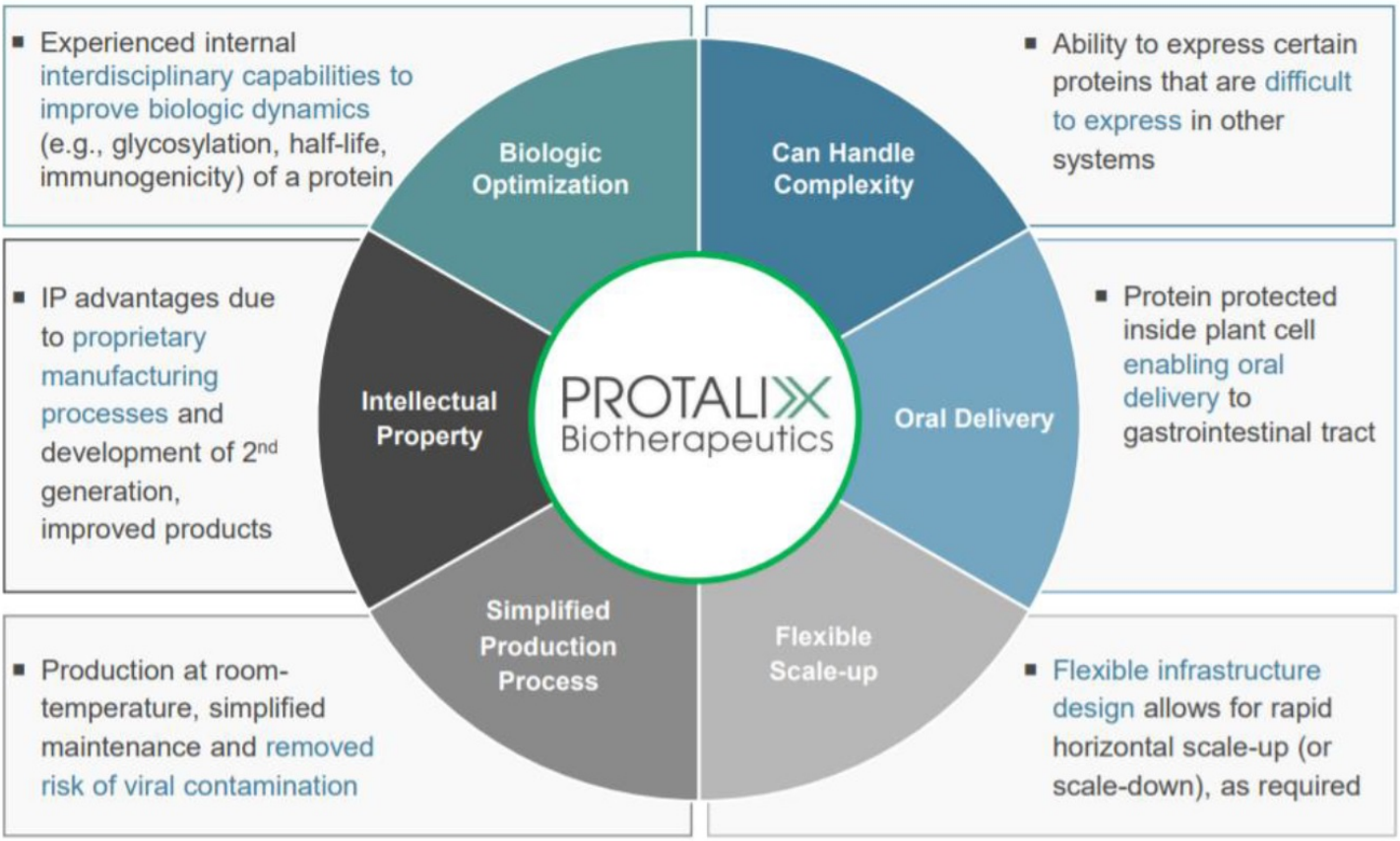
ProCellEx: Our Proprietary Protein Expression System

· ProCellEx is our proprietary platform used to produce proteins through plant cell cultures, which allows for unique advantages in the areas of intellectual property, manufacturing enhancements and product candidate characteristics with reduced risks for viral contaminations from mammalian components.

· We are the first and only company to gain FDA approval of a protein produced through plant cell-based expression. Our ProCellEx platform uses flexible polyethylene disposable bioreactors and is optimized for plant cell cultures. As opposed to the large stainless-steel bioreactors commonly used for recombinant protein production, our ProCellEx bioreactors are easy to use and maintain and allow for the major advantage of rapid horizontal scale-up.

Plant Cell Production Advantages Versus Mammalian Cell Production





Pegunigalsidase Alfa (PRX-102) for the Treatment of Fabry Disease

PRX-102 is our proprietary, investigational, plant cell culture expressed enzyme, and a chemically modified stabilized version of, the recombinant alpha-Galactosidase-A protein under development for the treatment of Fabry disease. Fabry disease is an X-linked inherited disease that results from deficient activity of the lysosomal enzyme alpha galactosidase A resulting in progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide (Gb3) in blood vessel walls throughout a person's body. Fabry disease occurs in one person per 40,000. Fabry patients inherit a deficiency of the enzyme alpha-galactosidase-A, which is normally responsible for the breakdown of Gb3. The abnormal storage of Gb3 increases with time and, accordingly, Gb3 accumulates, primarily in the blood and in the blood vessel walls. The ultimate consequences of Gb3 deposition range from episodes of pain and impaired peripheral sensation to end-organ failure – particularly of the kidneys, but also of the heart and the cerebrovascular system. Global sales of Fabry treatments exceeded $1.4 billion in 2018.

We, together with Chiesi, plan the submission of a BLA for PRX 102 by April 2020 through the FDA's Accelerated Approval pathway. This decision is the result of a series of meetings and correspondence between our company and Chiesi, on the one hand, and the FDA, on the other hand. We and Chiesi have initiated preparations for the BLA submission based on clinical data generated in the one-year completed phase I/II clinical trials of PRX-102 and from the ongoing phase III BRIDGE clinical trial, as well as safety data from all on-going studies. The BLA will also include extensive data from our completed nonclinical program, as well as information regarding production of PRX-102.

In December 2017, the European Commission granted Orphan Drug Designation for PRX-102 for the treatment of Fabry disease. Orphan Drug Designation for PRX-102 qualifies Chiesi 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 PRX-102 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.

Key Trials and Design

Our phase III clinical program of PRX-102 of the treatment of Fabry disease includes three individual studies; the BALANCE, BRIDGE and BRIGHT studies. In 2015, we completed a phase I/II clinical trial of PRX-102. In the phase III clinical program, we are studying two alternative dosing regimens for PRX-102 with the potential for improved efficacy and lower treatment burden versus existing treatments. The 1 mg/kg every two-weeks regimen offers the potential for superior enzyme replacement therapy while the 2 mg/kg every four weeks regimen offers the potential for better quality of life. Enrolment has been completed in each of the BALANCE, BRIDGE and BRIGHT studies.

Phase I/II Study

Our phase I/II clinical trial of PRX-102, which we completed in 2015, was a worldwide, multi-center, open label, dose ranging study to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and efficacy parameters of PRX-102 in adult Fabry patients. Sixteen adult naive Fabry patients (9 male and 7 female) completed the trial, each in one of three dosing groups, 0.2 mg/kg, 1mg/kg and 2mg/kg. Each patient received intravenous infusions of PRX-102 every two weeks for 12 weeks, with efficacy follow-up after six-month and twelve-month periods. All patients that completed the trial opted to continue to receive 1 mg/kg of PRX-102 in an open-label, 60-month extension study under which all patients have been switched to receive 1 mg/kg of the drug, the selected dose for our phase III studies of PRX-102.

The data set forth below was recorded at 24 months from 11 patients enrolled and treated in the long-term open-label extension trial. Patients who did not continue in the extension trial included female patients who became or planned to become pregnant, and therefore were unable to continue in accordance with the study protocol, and patients that relocated to a location where treatment was not available under the clinical study.

Lyso Gb3 levels decreased approximately 90% from baseline. Renal function remained stable with mean eGRF levels of 108.02 and 107.20 at baseline and 24 months, respectively with a modest annual eGFR slope of -2.1. An improvement across all the gastrointestinal symptoms evaluated, including severity and frequency of abdominal pain and frequency of diarrhea, were noted. Cardiac parameters, including LVM, LVMI and EF, remained stable with no cardiac fibrosis development detected. In conclusion, an improvement of over 40% in disease severity was shown as measured by the Mainz Severity Score Index (MSSI), a score compiling the different elements of the disease severity including neurological, renal and cardiovascular parameters. In addition, an improvement was noted in each of the individual parameters of the MSSI.

The majority of adverse events were mild to moderate in severity, and transient in nature. During the first 12 months of treatment, only three of 16 patients (less than 19%) formed anti-drug antibodies (ADA), of which two of these patients (less than 13%) had neutralizing antibodies. Importantly, however, the ADAs turned negative for all three of these patients following 12 months of treatment. The ADA positivity effect had no observed impact on the safety, efficacy or continuous biomarker reduction of PRX-102.

BALANCE Study

The BALANCE Study is a 24-month, randomized, double blind, active control study of PRX-102 in Fabry disease patients with impaired renal function. Patients previously treated with agalsidase beta for approximately one year and on a stable dose for at least six months were screened and then randomized to be switched and treated with 1 mg/kg of PRX-102 or continue treatment with 1mg/kg of agalsidase beta. Patients receive intravenous infusions of 1mg/kg administered every two weeks. Patients are randomized in a 2:1 ratio to PRX-102 or agalsidase beta. In the study, randomization is being stratified by urinary protein to creatinine ratio (UPCR) of $<$ or $\geq$ 1 g/g by spot urine sample. No more than 50% of the patients enrolled in the study are female. Patients participating in the study are being evaluated to, among other disease parameters, determine if their renal function continues to deteriorate at the same rate while being treated with agalsidase beta as measured by eGFR slope. Cardiac assessment, Lyso-Gb3, pain, quality of life, immunogenicity, clinical events and pharmacokinetic and other parameters are also being evaluated. In addition, participating patients are being evaluated to assess the safety and tolerability of PRX-102.

The primary endpoint for the BALANCE study, which was agreed with both the FDA and the EMA, is the comparison in the rate of decline of eGFR slope between agalsidase beta and PRX-102. At 12 months, we intend to conduct an interim analysis to test for non-inferiority to support an anticipated regulatory filing with the EMA. At the same time, we intend to approach the FDA to request its review of the then totality of data. Notwithstanding, patients enrolled in the study will continue to be treated for a total of 24 months, at which point the data will be analyzed to test for superiority, which is the original guidance we received from the FDA.

BRIDGE Study

The BRIDGE study is an open label switch-over study evaluating the safety and efficacy of PRX-102, 1 mg/kg infused every two weeks, in up to 22 Fabry patients currently treated with agalsidase alfa for at least two years and on a stable dose for at least six months. Patients are screened and evaluated over three months while continuing agalsidase alfa treatment. Following the screening period, each patient was enrolled and switched from agalsidase alfa treatment to receive intravenous (IV) infusions of PRX-102 1 mg/kg every two weeks for 12 months. Patients have the option to receive PRX-102 infusions in a home care setting based on infusion tolerability and country regulation.

An interim analysis of the BRIDGE study will be used to support the expected BLA filing under Accelerated Approval, and we anticipate that the final analysis will be used to support a marketing authorization application (MAA) with the EMA.

The 12-month interim data from the first 16 of 22 adult patients enrolled (9 males and 7 females) demonstrated a mean improvement in kidney function, in both male and female patients, when switched from agalsidase alfa to PRX-102.

One hundred percent of the progressing patients, those with an estimated Glomerular Filtration Rate (eGFR) slope between -5 and -3 mL/min/1.73 m^2/year, and 66.7% in the fast progressing group, with an eGFR slope < -5 mL/min/1.73 m^2/year, achieved the proposed therapeutic goals (eGFR slope ≥ -3 mL/min/1.73 m^2/year for progressing patients, and ≥ -5 mL/min/1.73m^2/year or more than 50% decrease in progression for fast progressing patients) after switching to PRX-102. The majority of the patients who completed the study rolled over to a long-term extension study, continuing to be treated with PRX-102.

In the study, after one year, the mean annualized eGFR slope improved from -5.10 mL/min/1.73m^2/year while on agalsidase alfa to -0.23 mL/min/1.73m^2/year on PRX-102. Baseline characteristics of these patients, ages 27 to 60 years, were: mean eGFR 75.45 in males and 85.78 mL/min/1.73m^2 in females, annualized pre-switching eGFR slope was -5.04 and -5.18 mL/min/1.73m^2/year, in males and females respectively, mean residual leucocytes enzymatic activity 5.9% of lab normal mean in males and 27.9% in females, and plasma lyso-Gb3 mean levels 53.6 and 13.8 nM, in males and females, respectively.

PRX-102 was found to be well tolerated in the study, with all adverse events being transient in nature without sequelae. Most of the patients who were eligible for home care therapy per country regulation were treated under a home care arrangement in which certain of the scheduled infusions were performed at the patients' home.

BRIGHT Study

The BRIGHT study is a 12 month, open-label switchover study to assess the safety, efficacy and pharmacokinetics (PK) of PRX-102 2 mg/kg administered every 4 weeks in up to 30 Fabry patients previously treated with an enzyme replacement therapy (ERT): agalsidase alfa or agalsidase beta. To determine eligibility for participation in the study, candidates were screened to identify and select Fabry patients with stable kidney disease. Patients that matched the criteria were enrolled in the study and switched from their current treatment of intravenous (IV) infusions every 2 weeks to 2 mg/kg of PRX-102 every 4 weeks for 12 months.

Patients participating in the study were evaluated to, among other disease parameters, determine if their kidney disease has not further deteriorated while being treated with the four-week dosing regimen as measured by eGFR and Lyso Gb3, as well as other parameters. In addition, participating patients were evaluated to assess the safety and tolerability of PRX-102.

To date, substantially all patients that were enrolled in the BRIGHT study remain on the 4-week dosing regimen, and all of the patients that completed the study opted, with the advice of the treating physician, to continue treatment under the 4-week dosing regimen in a long-term extension study.

Commercialization Agreements with Chiesi Farmaceutici

On October 19, 2017, Protalix Ltd. 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 PRX-102. 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 PRX-102 from Protalix Ltd., 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 PRX-102.

On July 23, 2018, Protalix Ltd. entered into the Chiesi US Agreement with respect to the development and 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.

Elelyso® for the Treatment of Gaucher Disease

Elelyso (taliglucerase alfa), our first commercial product, was approved by the FDA in 2012 for injection as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. In August 2014, the FDA approved Elelyso for injection for pediatric patients. Elelyso is the first plant cell derived recombinant protein to be approved by the FDA for the treatment of Gaucher disease and is now approved in over 20 markets.

Gaucher disease is a $1.5 billion global annual therapeutic market that includes Sanofi's Cerezyme®, Shire's (acquired by Takeda Pharmaceutical Company Limited) Vpriv® and Sanofi's Cerdelga®.

Commercialization Agreements for Elelyso

We have licensed to Pfizer the global rights to Elelyso in all markets excluding Brazil. Pfizer retains 100% of revenue and reimburses 100% of direct costs. We manufacture drug substance for Pfizer, subject to certain terms and conditions.

For the first 10-year period after the execution of our 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.

We maintain distribution rights to Elelyso in Brazil (marketed as alfataliglicerase) through a supply and technology transfer agreement with Fiocruz, an arm of the Brazilian Ministry of Health. Sales of alfataliglicerase in Brazil are expected to be $9.1 million for 2019.

OPRX-106 for the Treatment of Inflammatory Bowel Disease

OPRX-106 is a plant cell-expressed recombinant human tumor necrosis factor receptor II fused to an IgG1 Fc domain (TNFRII-Fc), for inhibiting TNF alpha. It is in development for oral administration. When administered orally and while passing through the digestive tract, the plant cells function as a natural delivery vehicle, having the unique attribute of a cellulose cell wall, which makes them resistant to degradation compared to proteins produced via mammalian cell expression.

Through oral administration, OPRX-106 is designed to work locally in the gut, avoiding the systemic exposure that occurs when TNF alpha inhibitors are administered by injection or intravenous infusion. Oral administration may potentially lead to a safer to use anti-TNF.

OPRX-106 may also be less immunogenic which can potentially result in longer-term efficacy.

We believe that our oral delivery mechanism can potentially prove to be a safer and more convenient method of protein administration and could be applied to additional proteins in certain indications.

Alidornase Alfa (PRX-110)

Alidornase alfa (PRX-110) is a proprietary plant cell-expressed recombinant form of human deoxyribonuclease I (DNase I). In cystic fibrosis (CF) patients, the accumulation of sputum in the lungs exposes them to recurrent infections and compromises lung function. DNase I therapy, or dornase alfa, is generally recommended for CF patients to improve lung function and reduce exacerbations.

However, DNase I activity is compromised by actin, a globular multi-functional protein, found in high concentration in the sputum of CF patients, that is a potent inhibitor of DNase I. As such, we believe that actin may decrease the enzyme's DNA degradation activity and potentially interfere with the effectiveness of inhaled DNase I in the lungs of CF patients.

In order to reduce the actin-DNase I interaction and the subsequent inhibition of DNase I activity by actin, we developed alidornase alfa by chemically modifying the enzyme forming an actin inhibition resistant DNase I. This novel treatment candidate may result in improved lung function and decreased incidence of recurrent infections in patients. Thus, we believe there is the potential that our recombinant form of the enzyme will demonstrate significantly enhanced efficacy.

Intellectual Property 2019

A key element of our overall strategy is to establish a broad portfolio of patents to protect our proprietary technology, proprietary product and product candidates and their methods of use. We hold a broad portfolio of more than 75 patents in Europe, the United States, Israel and additional countries worldwide, as well as more than 20 pending patent applications.

During 2019, patents were granted in Canada, India and the United States for the patent family named "Large Scale Disposable Bioreactor," adding these to the 11 previously granted patents in this family. Patents were also granted in India and the United States for the patent family named "Stabilized Alpha-Galactosidase and Uses Thereof" adding these to the 18 previously granted patents in this family. Another patent was granted in the United States for the patent family named "Nucleic acid construct for expression of Alpha-Galactosidase in plants and plant cells," adding these to the seven previously granted patents in this family. In addition, national phase filings were performed in certain countries worldwide for the patent family named "Therapeutic Regimen For The Treatment Of Fabry using Stabilized Alpha-Galactosidase." An Israeli patent was granted for the patent family named "Dry powder formulations of DNAse" adding to the already granted U.S. patent in this family.

Scientific Presentations 2019

On February 7, 2019, Mr. Myrl D. Holida, PA, of the University of Iowa Health Care in Iowa City, Iowa, a principal investigator in our phase III clinical trials of PRX-102, delivered an oral presentation entitled "Once every 4 weeks – 2 mg/kg of pegunigalsidase alfa for treating Fabry disease; Preliminary results of a Phase 3 study," highlighting preliminary PK and safety data from our BRIGHT study. The presentation was delivered at the 15th Annual WORLD*Symposium*™ 2019, which took place February 4-8, 2019.

In addition to the oral presentation, the following poster presentations were delivered at the conference with respect to PRX-102:

- "Once every 4 weeks – 2 mg/kg of pegunigalsidase alfa for treating Fabry disease; Preliminary results of a phase 3 study," by Myrl D. Holida.

- "Pegunigalsidase alfa for the treatment of Fabry disease: Preliminary results from a phase III open label, switch over study from agalsidase alfa," by Prof. Ales Linhart of the Všeobecná fakultní nemocnice v Praze, Prague Czech Republic, a principal investigator in our phase III clinical trials of PRX-102.

- "Analysis of the baseline characteristics of Fabry disease patients screened for the pegunigalsidase alfa phase III BALANCE study," by Prof. David Warnock, Professor of Nephrology at the University of Alabama Birmingham, Birmingham, Alabama, a consultant to our company.

Research & Development

We continuously work on the further development of our ProCellEx plant cell expression technology and bioreactor system. In addition, we are working on the development of new products, each in different initial stages of development, for specific products for which there are unmet needs in terms of efficacy and safety. Our development strategy focuses on the utilization of different modification approaches and development improvements, customized for each protein product, in all stages of expression and development.

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 September 30, 2019 compared to the three months ended September 30, 2018

Revenues from Selling Goods

We recorded revenues from selling goods of $5.1 million during the three months ended September 30, 2019, an increase of $4.5 million, or 673%, compared to revenues of $663,000 for the three months ended September 30, 2018. The increase resulted primarily from an increase of $3.2 million in sales of drug product to Brazil as well as an increase of $1.3 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 $9.1 million for the three months ended September 30, 2019, a decrease of $2.6 million, or 22%, compared to revenues of $11.7 million for the three months ended September 30, 2018. Revenues from the license agreements represent the revenues we recognized in connection with the Chiesi Agreements. The decrease resulted primarily from a cumulative catch-up adjustment of $6.2 million in the third quarter of 2018 due to the Chiesi US Agreement, which we entered into on July 23, 2018.

Cost of Goods Sold

Cost of goods sold was $3.2 million for the three months ended September 30, 2019, an increase of $1.3 million, or 67%, from cost of goods sold of $1.9 million for the three months ended September 30, 2018. The increase is primarily due to an increase in sales of goods.

Research and Development Expenses, Net

Research and development expenses were $10.0 million for the three months ended September 30, 2019, similar to the $10.1 million of research and development expenses for the three months ended September 30, 2018.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.6 million for the three months ended September 30, 2019, a decrease of $1.5 million, or 37%, compared to $4.1 million for the three months ended September 30, 2018. The decrease is primarily due to costs related to the Chiesi US Agreement we entered into in the third quarter of 2018, which were not incurred in the third quarter of 2019.

Financial Expenses, net

Financial expenses net were $2.0 million for the three months ended September 30, 2019, an increase of $0.4 million, or 28%, compared to financial expenses net of $1.6 million for the three months ended September 30, 2018. Financial expenses are comprised primarily of interest expense on our outstanding convertible notes of $1.1 million for the three months ended September 30, 2019 and 2018. The increase is primarily due to exchange rate differences.

Nine months ended September 30, 2019 compared to the nine months ended September 30, 2018

Revenues from Selling Goods

We recorded revenues from selling goods of $12.1 million during the nine months ended September 30, 2019, an increase of $4.9 million, or 67%, compared to revenues of $7.2 million for the nine months ended September 30, 2018. The increase resulted primarily from an increase of $4.8 million in sales of drug product to Brazil as well as an increase of $52,000 in sales of drug substance to Pfizer.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $24.8 million for the nine months ended September 30, 2019, an increase of $8.1 million, or 49%, compared to revenues of $16.7 million for the nine months ended September 30, 2018. Revenues from the license agreements represent the revenues we recognized in connection with the Chiesi Agreements. The increase is primarily due to revenues recognized in connection with the Chiesi US Agreement which we entered into on July 23, 2018.

Cost of Goods Sold

Cost of goods sold was $7.9 million for the nine months ended September 30, 2019, an increase of $0.9 million, or 13%, from cost of goods sold of $7.0 million for the nine months ended September 30, 2018. The increase is primarily due to an increase in sales of goods.

Research and Development Expenses, Net

Research and development expenses were $35.0 million for the nine months ended September 30, 2019, an increase of $11.3 million, or 47%, compared to $23.8 million of research and development expenses for the nine months ended September 30, 2018. The increase resulted primarily from an increase of $8.5 million in clinical trial related costs as well as a decrease of $1.8 million in grants received from the Israeli Innovation Authority.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $6.9 million for the nine months ended September 30, 2019, a decrease of $1.9 million, or 21%, compared to $8.7 million for the nine months ended September 30, 2018. The decrease is primarily due to costs related to the Chiesi US Agreement we entered into in the third quarter of 2018, which were not incurred in the third quarter of 2019.

Financial Expenses, net

Financial expenses net were $5.7 million for the nine months ended September 30, 2019, an increase of $0.3 million, or 5%, compared to financial expenses net of $5.4 million for the nine months ended September 30, 2018. Financial expenses are comprised primarily of interest expense on our outstanding convertible notes of $3.3 million for the nine months ended September 30, 2019 and 2018. The increase is primarily due to exchange rate differences.

Liquidity and Capital Resources

Sources of Liquidity

Our sources of liquidity include our cash balances. At September 30, 2019, we had $21.4 million in cash and cash equivalents. We have primarily financed our operations through equity and debt financings, business collaborations, and grant funding. 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.

On October 16, 2019, we received total proceeds of approximately $2.6 million from expense reimbursements in relation to our collaboration with Chiesi and on October 18, 2019, we received total proceeds of approximately $3.2 million from sales of alfataliglicerase to Fiocruz.

Cash Flows

Net cash used in operations was $15.7 million for the nine months ended September 30, 2019. The net loss for the nine months ended September 30, 2019 of $18.6 million was further increased by a $4.8 million increase in accounts receivable, but was partially offset by an increase of $4.9 million in accounts payable and accruals and by a decrease in inventories of $1.0 million. Net cash used in investing activities for the nine months ended September 30, 2019 was $0.9 million and consisted primarily of purchases of property and equipment, and an increase in restricted deposit.

Net cash used in operations was $3.7 million for the nine months ended September 30, 2018. The net loss for the nine months ended September 30, 2018 of $21.0 million was partially offset by an increase of $18.3 million in contracts liabilities representing an upfront payment and certain expense reimbursements actually received from Chiesi in connection with our license agreements with Chiesi which we have not yet recognized as revenues. Net cash used in investing activities for the nine months ended September 30, 2018 was $675,000 and consisted primarily of purchases of property and equipment, and an increase in restricted deposit. Net cash used in financing activities was $4.8 million for the repayment of convertible notes.

Future Funding Requirements

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. We currently have outstanding $57.9 million aggregate principal amount of our 2021 Notes that are secured with a perfected lien on all of our assets. Under the terms of the indenture governing the 2021 Notes, we are required to maintain a minimum cash balance of at least $7.5 million. These factors raise substantial doubt as to our ability to continue as a going concern. In addition, as previously disclosed, we have received a deficiency letter from the NYSE American stating that we are not in compliance with the continued listing standards as set forth in Section 1003(a)(i) – (iii) of the NYSE American Company Guide as we have reported a stockholders' equity deficiency as of June 30, 2019 and net losses in our five most recent fiscal years ended December 31, 2018. The letter has no immediate effect on the listing of our common stock on the NYSE American. Our common stock will trade on the NYSE American while we regain compliance with the continued listing standards.

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. Our material cash needs for the next 24 months will include, among other expenses, (i) costs of preclinical and clinical trials, (ii) employee salaries, (iii) payments for rent and operation of our manufacturing facilities, (iv) fees to our consultants and legal advisors, patents and fees for service providers in connection with our research and development efforts and (v) payment of principal and interest on our outstanding convertible promissory notes and other debt.

We will be required to raise a substantial amount of capital in the future in order to develop and commercialize our product candidates and continue research and development activities. Our ability to raise capital, and the amounts of necessary capital, will depend on many other factors, including:

- our ability to maintain the listing of our common stock with the NYSE American;
- our efforts to commercialize PRX-102, and those of Chiesi;
- our progress in commercializing alfataliglicerase in Brazil;
- the costs of commercialization activities, including product marketing, sales and distribution;
- the progress and results of our clinical trials, particularly our clinical trials of PRX-102;
- 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; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights.

We expect to finance our future cash needs through corporate collaborations, 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.

Our management is in the process of evaluating refinancing and restructuring alternatives, including a restructuring of our outstanding convertible notes, and related transactions. However, there is no certainty about our ability to obtain such funding.

The financial information has been prepared on a going concern basis, which assumes we will continue to realize our assets and discharge our liabilities in the normal course of business. If we do not raise the requisite funds, we will need to curtail or cease operations. These financial statements do not include any adjustments that may be necessary should we be unable to continue as a going concern.

Effects of Currency Fluctuations

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services. We do not believe currency fluctuations have had a material effect on our results of operations during the nine months ended September 30, 2019 and September 30, 2018.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2019 and September 30, 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:

	Nine Months Ended September 30,		Year Ended December 31,
	2019	2018	2018
Average rate for period	3.589	3.558	3.595
Rate at period end	3.482	3.627	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.

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.

Changes in Internal Control over Financial Reporting

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 September 30, 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

Except as set forth below, 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 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019.

We have received a Deficiency Letter from the NYSE American regarding our common stock.

On August 30, 2019, we announced that we received a deficiency letter from the NYSE American stating that we are not in compliance with the continued listing standards as set forth in Section 1003(a)(i) – (iii) of the NYSE American Company Guide as we have reported a stockholders' equity deficiency as of June 30, 2019 and net losses in our five most recent fiscal years ended December 31, 2018, which may result in the delisting of our common stock from the NYSE American. The letter has no immediate effect on the listing of our common stock on the NYSE American. Our common stock will trade on the NYSE American while we regain compliance with the continued listing standards. Subsequently, we submitted a detailed plan of compliance advising the NYSE American of the actions we have taken, or plan to take, that would bring our company into compliance with the continued listing standards within 18 months of receipt of the letter.

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

There were no unregistered sales of equity securities during the nine months ended September 30, 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	
10.1	Employment Agreement made effective as of July 28, 2019 by and between Protalix Ltd. and Eyal Rubin	8-K	001-33357	10.1	July 29, 2019	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer					X
32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer					X
101.INS	XBRL INSTANCE FILE					X

101.SCH	XBRL SHEMA FILE	X
101.CAL	XBRL CALCULATION FILE	X
101.DEF	XBRL DEFINITION FILE	X
101.LAB	XBRL LABEL FILE	X
101.PRE	XBRL PRESENTATION FILE	X

SIGNATURES

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

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: November 7, 2019

By: /s/ Dror Bashan
Dror Bashan
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2019

By: /s/ Eyal Rubin
Eyal Rubin
Senior Vice President and Chief Financial Officer, Treasurer and Secretary
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, Dror Bashan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2019

/s/ Dror Bashan

Dror Bashan
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Eyal Rubin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2019

/s/ Eyal Rubin

Eyal Rubin
Sr. Vice President & Chief Financial Officer, Treasurer

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Dror Bashan, President and Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

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

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

Date: November 7, 2019

/s/ Dror Bashan

Dror Bashan
President and Chief Executive Officer

EXHIBIT 32.2

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Eyal Rubin, Senior Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

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

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

Date: November 7, 2019

/s/ Eyal Rubin
Eyal Rubin
Senior Vice President and Chief Financial Officer