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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2020

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)	**2161401 (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, par value $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 October 15, 2020, approximately 33,336,709 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)
(Unaudited)

	September 30, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,533	$ 17,792
Short-term bank deposits	27,760	-
Accounts receivable – Trade	3,146	4,700
Other assets	2,612	1,832
Inventories	13,281	8,155
Total current assets	$ 60,332	$ 32,479
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	1,639	$ 1,963
Property and equipment, net	4,639	5,273
Operating lease right of use assets	5,700	5,677
Total non-current assets	$ 11,978	$ 12,913
Total assets	$ 72,310	$ 45,392
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 8,351	$ 6,495
Other	13,347	11,905
Operating lease liabilities	1,176	1,139
Contracts liability	16,720	16,335
Promissory note	4,301	4,301
Total current liabilities	$ 43,895	$ 40,175
LONG TERM LIABILITIES:		
Convertible notes	$ 53,505	$ 50,957
Contracts liability	1,533	16,980
Liability for employee rights upon retirement	2,088	2,565
Operating lease liabilities	4,558	4,528
Other long term liabilities	46	509
Total long term liabilities	$ 61,730	$ 75,539
Total liabilities	$ 105,625	$ 115,714
COMMITMENTS		
CAPITAL DEFICIENCY	(33,315)	(70,322)
Total liabilities net of capital deficiency	$ 72,310	$ 45,392

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, 2020	September 30, 2019	September 30, 2020	September 30, 2019
REVENUES FROM SELLING GOODS	$ 11,975	$ 12,086	$ 3,296	$ 5,126
REVENUES FROM LICENSE AND R&D SERVICES	31,428	24,848	7,494	9,122
TOTAL REVENUE	43,403	36,934	10,790	14,248
COST OF GOODS SOLD	(8,121)	(7,945)	(2,868)	(3,205)
RESEARCH AND DEVELOPMENT EXPENSES, NET (1)	(27,214)	(35,021)	(7,688)	(10,000)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(8,197)	(6,885)	(2,816)	(2,587)
OPERATING LOSS	(129)	(12,917)	(2,582)	(1,544)
FINANCIAL EXPENSES	(7,150)	(5,877)	(1,973)	(2,050)
FINANCIAL INCOME	359	227	118	34
FINANCIAL EXPENSES - NET	(6,791)	(5,650)	(1,855)	(2,016)
NET LOSS FOR THE PERIOD	$ (6,920)	$ (18,567)	$ (4,437)	$ (3,560)
NET LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED	$ (0.25)	$ (1.25)	$ (0.14)	$ (0.24)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	27,758,104	14,838,213	32,863,788	14,838,213
(1) Includes share-based compensation	$ 635	$ 426	$ 562	$ 110
(2) Includes share-based compensation	$ 1,477	$ 173	$ 852	$ 86

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, 2019	**14,838,213**	**$ 15**	**$ 269,657**	**$ (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	**14,838,213**	**$ 15**	**$ 270,256**	**$ (341,120)**	**$ (70,849)**
Balance at January 1, 2020	**14,838,213**	**$ 15**	**$ 270,492**	**$ (340,829)**	**$ (70,322)**
Changes during the nine-month period ended September 30, 2020:					
Issuance of common stock and warrants, net of issuance cost	17,604,423	18	41,325		41,343
Share-based compensation related to stock options			1,607		1,607
Share-based compensation related to restricted stock awards	694,073		505		505
Exercise of warrants	200,000	*	472		472
Net loss for the period				(6,920)	(6,920)
Balance at September 30, 2020	**33,336,709**	**$ 33**	**$ 314,401**	**$ (347,749)**	**$ (33,315)**
Balance at June 30, 2019	**14,838,213**	**$ 15**	**$ 270,060**	**$ (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	**14,838,213**	**$ 15**	**$ 270,256**	**$ (341,120)**	**$ (70,849)**
Balance at June 30, 2020	**32,442,636**	**$ 33**	**$ 308,515**	**$ (343,312)**	**$ (34,764)**
Changes during the three-month period ended September 30, 2020:					
Note receivable payment			4,000		4,000
Share-based compensation related to stock options			909		909
Share-based compensation related to restricted stock awards	694,073		505		505
Exercise of warrants	200,000	*	472		472
Net loss for the period				(4,437)	(4,437)
Balance at September 30, 2020	**33,336,709**	**$ 33**	**$ 314,401**	**$ (347,749)**	**$ (33,315)**

* Represents an amount less than $1.
(1) Common Stock, $0.001 par value; Authorized – as of September 30, 2020 and 2019 - 120,000,000 and 350,000,000, 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, 2020	September 30, 2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (6,920)	$ (18,567)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	2,112	599
Depreciation	1,011	1,205
Financial expenses (income), net (mainly exchange differences)	(284)	371
Changes in accrued liability for employee rights upon retirement	(488)	51
Gain on amounts funded in respect of employee rights upon retirement	(11)	—
Amortization of debt issuance costs and debt discount	2,548	2,197
Changes in operating assets and liabilities:		
Decrease in contracts liability (including non-current portion)	(15,062)	(2,697)
Decrease (increase) in accounts receivable and other assets	783	(4,767)
Changes in right of use assets	53	(92)
Decrease (increase) in inventories	(5,126)	1,044
Increase in accounts payable and accruals	3,291	4,905
Increase (decrease) in other long term liabilities	(463)	80
Net cash used in operating activities	$ (18,556)	$ (15,671)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Increase in bank deposits	$ (27,500)	$ —
Purchase of property and equipment	(380)	(599)
Increase in restricted deposit	(4)	(254)
Amounts funded in respect of employee rights upon retirement, net	340	(59)
Net cash used in investing activities	$ (27,544)	$ (912)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock and warrants, net of issuance cost	$ 41,343	$ —
Exercise of warrants	472	
Net cash provided by financing activities	$ 41,815	$ —
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ 26	$ 217
NET DECREASE IN CASH AND CASH EQUIVALENTS	(4,259)	(16,366)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	17,792	37,808
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 13,533	$ 21,442

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, 2020	September 30, 2019
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 95	$ 14
Right of use assets obtained in exchange for new operating lease liabilities	$ 564	

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

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the "Company") and its wholly-owned subsidiaries, Protalix Ltd. and Protalix B.V. (collectively, 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 BioManguinhos 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 most advanced investigational drug in the Company's product pipeline is pegunigalsidase alfa, or PRX-102, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder. A biologics license application (BLA) PRX-102 for the treatment of adult patients with Fabry disease was submitted to the U.S. Food and Drug Administration (the "FDA") on May 27, 2020 under the FDA's Accelerated Approval pathway. On August 11, 2020, the Company, together with its development and commercialization partner for PRX-102, Chiesi Farmaceutici S.p.A. ("Chiesi"), announced that the FDA had accepted the BLA and granted Priority Review designation for PRX-102 for the proposed treatment of adult patients with Fabry disease. The FDA also indicated in the BLA filing communication letter that it is not currently planning to hold an advisory committee meeting to discuss the application. The FDA set an action date of January 27, 2021, under the Prescription Drug User Fee Act (PDUFA). The FDA advised that it will have to inspect the Company's manufacturing facility and the facility of a third party in Europe that performs fill and finish processes for PRX-102 as part of the FDA's review of the BLA application. Due to COVID-19 related FDA travel restrictions, the FDA has advised that it may be unable to conduct the inspections prior to the PDUFA date. The Company, together with Chiesi, is in active dialogue with the FDA and have submitted a request to the FDA for a Type A meeting to seek resolution on the issue of the pre-license inspections of the two manufacturing facilities. The Company anticipates an FDA response to this request in the first week of November 2020.

In addition to PRX-102, the Company's product pipeline currently includes, among other candidates:

(1) alidornase alfa, or PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or DNase;

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

(3) PRX-115, the Company's plant cell-expressed recombinant PEGylated Uricase (Urate Oxidase) – a chemically modified enzyme to treat Gout.

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 1, 2020, the Company entered into an ATM Equity Offering℠ Sales Agreement (the "Sales Agreement") with BofA Securities, Inc., as the Company's sales agent (the "Agent"). Pursuant to the terms of the Sales Agreement, the Company may sell from time to time through the Agent shares of the Company's common stock having an aggregate offering price of up to $30 million (the "ATM Shares").

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (Continued)

On March 18, 2020, the Company completed a private placement of its common stock and warrants. In connection with the offering, the Company issued 17,604,423 unregistered shares of the Company's common stock, par value $0.001 per share (the "Common Stock"), at a purchase price per share of $2.485 and warrants to purchase an additional 17,604,423 shares of Common Stock at an exercise price of $2.36 per share. The warrants are exercisable commencing six months following their issuance for a period of five years from the date of issuance. For accounting purposes, the warrants are classified as equity considering the warrants' terms. The net proceeds generated from the private placement were approximately $41.3 million, after deducting advisory fees and other estimated offering expenses.

In October 2020, the Company collected total proceeds of approximately $2.7 million from accounts receivable outstanding at September 30, 2020; approximately $0.9 million in connection with its collaboration with Chiesi and approximately $1.8 million from sales to Pfizer Inc. ("Pfizer") under the exclusive license and supply agreement entered into between Protalix Ltd. and Pfizer (the "Pfizer Agreement").

On October 19, 2017, Protalix Ltd. and Chiesi entered into an Exclusive License and Supply Agreement (the "Chiesi Ex-US Agreement") pursuant to which Protalix Ltd. granted to Chiesi 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 additional payments of up to a maximum of $760.0 million, in the aggregate, in regulatory and commercial milestone payments. To date, Protalix Ltd. has received the complete amount of development costs to which it is entitled under the Chiesi Agreements.

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 Pfizer Agreement. In October 2015, Protalix Ltd. and Pfizer entered into an amended exclusive license and supply agreement (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 BioManguinhos 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 BioManguinhos alfataliglicerase to Fiocruz under the Brazil Agreement, and patients continue to be treated with BioManguinhos alfataliglicerase in Brazil.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company believes that its cash and cash equivalents and bank deposits as of September 30, 2020 are sufficient to satisfy the Company's capital needs for at least 12 months from the date that these financial statements are issued. In addition, as of September 30, 2020, there was outstanding an aggregate principal amount of the Company's 7.50% convertible secured promissory notes due November 15, 2021 equal to $57.9 million (the "2021 Notes"), unless the notes are refinanced, restructured or converted before that date.

The Company expects that by the maturity date of the 2021 Notes its cash and cash equivalents and short term deposits, combined with the cash the Company anticipates generating from the satisfaction of milestones under the Chiesi US Agreement and from its revenues, will be sufficient to satisfy the 2021 Notes payment. If, prior to the maturity date of the 2021 Notes, the Company will not have sufficient cash available to satisfy the full principal amount of the outstanding 2021 Notes, and to otherwise finance its future cash needs**,** management may pursue corporate collaborations, licensing or similar arrangements, public or private equity offerings, and/or debt financings or restructuring, sell shares under the Company's ATM Sales Agreement, and if necessary, may need to scale back operations, curtail or cease operations. Other than the ATM Sales Agreement, the Company does 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. There is no assurance that the Company will be successful in obtaining the level of financing needed for its operations.

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, 2019, filed by the Company with the U.S. Securities and Exchange Commission (the "Commission"). The comparative balance sheet at December 31, 2019 has been derived from the audited financial statements at that date.

c. 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 attributable to common stockholders outstanding for each period.

The calculation of diluted LPS does not include 7,826,946 and 21,405,733 shares of Common Stock underlying outstanding options and restricted shares of Common Stock and shares issuable upon conversion of outstanding convertible notes and outstanding warrants for the nine months ended September 30, 2019 and 2020, respectively, and 7,854,729 and 26,905,842 shares of Common Stock for the three months ended September 30, 2019 and 2020, respectively, because their effect would be anti-dilutive.

The computation of basic and diluted net loss per common stock was adjusted retrospectively for all periods presented to reflect the Company's reverse stock split at a ratio of one-for-ten, effective as of December 19, 2019.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (Continued)

d. Revenue recognition

Effective January 1, 2018, the Company adopted Accounting Standards Codification, Topic 606, Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, a contract with a customer exists only when: the parties to the contract have approved it and are committed to perform their respective obligations, the Company can identify each party's rights regarding the distinct goods or services to be transferred ("performance obligations"), the Company can determine the transaction price for the goods or services to be transferred, the contract has commercial substance and it is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer.

Revenues are recorded in the amount of consideration to which the Company expects to be entitled in exchange for performance obligations upon transfer of control to the customer.

1. Revenues from selling products

The Company recognizes revenues from selling goods at a point in time when control over the product is transferred to customers (upon delivery).

2. Revenue from Chiesi Agreements

The Company has identified two performance obligations in Chiesi agreements as follows: (1) the license and research and development services and (2) the contingent performance obligation regarding future manufacturing.

The Company determined that the license together with the research and development services should be combined into single performance obligation since Chiesi cannot benefit from the license without the research and development services. The research and development services are highly specialized and are dependent on the supply of the drug.

The future manufacturing is contingent on regulatory approvals of the drug and the Company deems these services to be separately identifiable from other performance obligations in the contract. Manufacturing services post-regulatory approval are not interdependent or interrelated with the license and research and development services.

The transaction price was comprised of fixed consideration and variable consideration (capped research and development reimbursements). Under ASC 606, the consideration to which the Company would be entitled upon the achievement of contractual milestones, which are contingent upon the occurrence of future events, are a form of variable consideration. The Company estimates variable consideration using the most likely method. Amounts included in the transaction price are recognized only when it is probable that a significant reversal of cumulative revenues will not occur. Prior to recognizing revenue from variable consideration, the Company uses significant judgment to determine the probability of significant reversal of such revenue.

Since the customer benefits from the research and development services as the entity performs the service, revenue from granting the license and the research and development services is recognized over time using the cost-to-cost method. The Company used significant judgment when it determined the costs expected to be incurred upon satisfying the identified performance obligation.

Revenue from additional research and development services ordered by Chiesi, is recognized over time using the cost-to-cost method.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES (Continued)

3. Revenue from R&D services

Revenue from the research and development services is recognized over time using the cost-to-cost method since the customer benefits from the research and development services as the entity performs the service.

e. Recently issued accounting pronouncements

In June 2016, the Financial Accounting Standards Board issued an Accounting Standards Update that supersedes the existing impairment model for most financial assets to a current expected credit loss model. The new guidance requires an entity to recognize an impairment allowance equal to its current estimate of all contractual cash flows the entity does not expect to collect. The Company adopted this guidance effective January 1, 2020, with no material impact on its consolidated financial statements.

NOTE 2 - INVENTORIES

Inventories at September 30, 2020 and December 31, 2019 consisted of the following:

(U.S. dollars in thousands)	September 30, 2020	December 31, 2019
Raw materials	$ 3,941	$ 3,607
Work in progress	2,782	552
Finished goods	6,558	3,996
Total inventory	$ 13,281	$ 8,155

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 (including the conversion option) is based on Level 3 measurement.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 3 – FAIR VALUE MEASUREMENT (Continued)

As of September 30, 2020, the carrying amounts of short-term and long-term deposits approximate their fair values due to the stated interest rates, which approximate market rates.

The fair value of the $59.7 million aggregate principal amount of the Company's outstanding 7.50% 2021 Notes as of September 30, 2020 is approximately $62.4 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, 2020. 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)	3.87
Expected term	1.13
Risk free rate	0.12 %
Volatility	100.20 %
Yield	12.34 %

NOTE 4 – REVENUES

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

(*U.S. dollars in thousands*)	Nine Months Ended September 30, 2020	2019
Pfizer	$ 5,844	$ 4,701
Brazil	$ 6,000	$ 7,385
Chiesi	$ 131	$ —
Total revenues from selling goods	$ 11,975	$ 12,086
Revenues from license and R&D services	$ 31,428	$ 24,848

During the nine months ended September 30, 2020, the Company recorded revenue in the amount of $6.7 million following a change in estimate of the total costs expected to be incurred in the connection with the Chiesi Agreements.

On March 16, 2020, the Company agreed to conduct a feasibility study with Kirin Holdings Company, Limited ("Kirin") to evaluate the production of a novel complex protein utilizing ProCellEx®, the Company's proprietary plant cell-based protein expression system. Kirin will bear the costs of conducting cell line engineering and protein expression studies on the target protein. In addition, the contract provides Kirin with an option to a future service for which the Company received a non-refundable payment in the amount of $1.0 million. The Company will recognize such amount as revenues when the aforementioned future services are performed or when the option expires.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 5 – STOCK TRANSACTIONS

a. On June 17, 2020, the Company granted, with the approval of the Company's compensation committee, the following:

1. 10-year options to purchase 196,995 shares of Common Stock to the Company's Sr. Vice President and Chief Development Officer under the Company's Amended and Restated 2006 Employee Stock Incentive Plan, as amended (the "Plan"). The options have an exercise price equal to $3.59 per share and vest over a four-year period in 16 equal quarterly increments. Vesting of the options granted to the Sr. Vice President and Chief Development Officer are subject to automatic 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's President and Chief Executive Officer may, in his discretion, grant options to the Company's Sr. Vice President and Chief Development Officer to purchase additional shares if the Company effects certain transactions in which it issues additional shares of Common Stock. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $0.5 million based on the following weighted average assumptions: share price equal to $3.59; dividend yield of 0% for all years; expected volatility of 80.43%; risk-free interest rate of 0.59%; and expected life of six years.

2. 10-year options to purchase 760,311 shares of Common, in the aggregate, to certain of the Company's employees under the Plan. The options granted have an exercise price equal to $3.66 per share and vest over a four-year period in 16 equal quarterly increments. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $1.9 million based on the following weighted average assumptions: share price equal to $3.66; dividend yield of 0% for all years; expected volatility of 80.49%; risk-free interest rate of 0.45%; and expected life of six years.

b. On August 11, 2020, the Company granted, with the approval of the Company's compensation committee, the following:

1. 447,927 shares of restricted Common Stock to its President, Chief Executive Officer under the Plan. The restricted shares vest over a four-year period in 16 equal quarterly increments and are subject to automatic acceleration in full upon a Corporate Transaction or a Change in Control, and are subject to certain other terms and conditions. The Company estimated the fair value of the restricted stock on the date of grant to be approximately $1.6 million.

2. 246,146 shares of restricted Common Stock to its Sr. Vice President, Chief Financial Officer under the Plan. Of the shares, 27,855 shares vested on September 22, 2020. The remaining 218,291 of the shares vest in 16 equal, quarterly increments over a four-year period, commencing upon the date of grant and are subject to automatic acceleration in full upon a Corporate Transaction or a Change in Control, and are subject to certain other terms and conditions. The Company estimated the fair value of the restricted stock on the date of grant to be approximately $0.9 million.

3. 10-year options to purchase 122,656 shares of Common Stock to the Company's Sr. Vice President, Operations under the Plan. The options have an exercise price equal to $3.59 per share and vest over a four-year period in 16 equal quarterly increments. Vesting of the options granted to the Sr. Vice President, Operations are subject to automatic acceleration in full upon a Corporate Transaction or a Change in Control, and are subject to certain other terms and conditions. The Company's President and Chief Executive Officer may, in his discretion, grant options to the Company's Sr. Vice President, Operations to purchase additional shares if the Company effects certain transactions in which it issues additional shares of Common Stock. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $0.3 million based on the following weighted average assumptions: share price equal to $3.59; dividend yield of 0% for all years; expected volatility of 80.51%; risk-free interest rate of 0.365%; and expected life of six years.

c. On September 14, 2020, the Company issued 200,000 shares of Common Stock in connection with the cash exercise of a warrant issued on March 18, 2020, as part of the Company's private placement of Common Stock and warrants. The Company generated net proceeds equal to $472,000 from the exercise of the warrant.

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 5 - STOCK TRANSACTIONS (Continued)

d. On October 1, 2020, the Company entered into the Sales Agreement with the Agent. Pursuant to the terms of the Sales Agreement, the Company may sell from time to time through the Agent ATM Shares having an aggregate offering price of up to $30 million. The ATM Shares will be issued pursuant to the Company's shelf registration statement on Form S-3 (Registration No. 333-230604). The Company intends to use the net proceeds from the offering, after deducting the Agent's commissions and the Company's offering expenses, for general corporate purposes.

NOTE 6 – PROMISSORY NOTE

In September 2020, the Company amended the outstanding $4.3 million promissory note payable to Pfizer by November 2020 to extend the maturity date to the earlier of (a) January 31, 2022 and (b) the date that the Company receive any milestone payment from Chiesi, if at all, subject to certain conditions and exceptions. The amendment also provides that the Company shall make a payment of $430,000 to Pfizer. The payment is creditable against the principal amount of the note, in whole or in part, if the Company satisfies the note in full on or prior to September 30, 2021, depending on the date the note is satisfied. The promissory note is presented under the short-term liabilities.

NOTE 7 – SUBSEQUENT EVENTS

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 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, 2019. 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 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, 2019, and in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020 and September 30, 2020.

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

- the timing, progress and likelihood of final approval by the FDA of the BLA for PRX-102, by the PDUFA date or at all, which was accepted by the FDA and granted Priority Review designation in August 2020 and, if approved, whether the use of PRX-102 will be commercially successful;

- the risk that the FDA, the European Medicines Agency, or EMA, or other foreign regulatory authorities may not accept or approve a marketing application we file for any of our product candidates;

- risks associated with the novel coronavirus disease, or COVID-19, outbreak, which may adversely impact our business, preclinical studies and clinical trials;

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

- the risk that the results of our clinical trials will not support the applicable claims of 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 evaluation and pursuit of strategic alternatives;

- 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;

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

- risks relating to our ability to execute a license agreement with SarcoMed USA Inc., or SarcoMed, with terms and conditions acceptable to us, if at all;

- 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 potential commercial value of our product and product candidates;
- potential product liability risks, and risks of securing adequate levels of related insurance coverage;
- 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;
- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; and
- the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

Recent Company Developments

- On August 11, 2020, we, together with Chiesi, announced that the FDA had accepted the BLA for PRX-102, and granted Priority Review designation for PRX-102, for the proposed treatment of adult patients with Fabry disease. The FDA also indicated in the BLA filing communication letter that it is not currently planning to hold an advisory committee meeting to discuss the application. The FDA set an action date of January 27, 2021, under the Prescription Drug User Fee Act (PDUFA). The FDA advised that it requires an inspection of our manufacturing facility and the facility of a third party in Europe that performs fill and finish processes for PRX-102 as part of the FDA's review of the BLA application. Due to COVID-19 related FDA travel restrictions, the FDA has advised that it may be unable to conduct the inspections prior to the PDUFA date. We, together with Chiesi, are in active dialogue with the FDA and have submitted a request to the FDA for a Type A meeting to seek resolution on the issue of the pre-license inspections of the two manufacturing facilities. We anticipate an FDA response to this request in the first week of November 2020.

- On August 24, 2020, we, together with Chiesi, announced completion of the treatment period of the Phase III BRIGHT clinical trial of pegunigalsidase alfa for the proposed treatment of Fabry disease. We anticipate announcing top-line results from the study by the end of the first quarter, 2021.

- On September 3, 2020, we received notification from the NYSE American LLC, or the NYSE American, that we had regained compliance with all of the continued listing standards set forth in Part 10 of the NYSE American Company Guide.

- On October 1, 2020, we entered into the ATM Equity Offering^{SM} Sales Agreement with BofA Securities, Inc., as the Agent. Pursuant to the terms of the Sales Agreement, we may sell from time to time through the Agent ATM Shares having an aggregate offering price of up to $30 million. We intend to use the net proceeds from the offering, after deducting the Agent's commissions and our offering expenses, for general corporate purposes.

- On October 2, 2020, we, together with Chiesi, announced launch of an Expanded Access Program (EAP) in the United States for pegunigalsidase alfa for the proposed treatment of Fabry disease.

We continue to actively advance all our clinical programs. We are in close contact with our principal investigators and clinical sites and our clinical research organizations, which are primarily located in the United States and Europe, and to date, our clinical trials have not been materially adversely affected by COVID-19. In light of recent developments relating to the COVID-19 pandemic, the focus of healthcare providers and hospitals on fighting the virus, and consistent with the FDA's updated industry guidance for conducting clinical trials issued on March 18, 2020, we and our contract research organizations have made certain adjustments to the operation of our clinical trials in an effort to ensure the monitoring and safety of patients and minimize risk to trial integrity during the pandemic and generally, and we may need to make further adjustments in the future.

In response to the local spread of COVID-19 at the end of March 2020, and with local directives issued in response thereof, we restructured the work day within our facilities to consist of two shifts thereby reducing the number of employees present in the facilities at any time and facilitating their ability to practice social distancing. Employees that were able to work from home were

instructed to do so. Such efforts resulted in minor delays in the performance of administrative activities outside of the clinical programs.

In June 2020, after local directives allowed more flexibility with respect to social interactions, we returned to a regular work day. Since then, as the pandemic's effect locally continued to change, and local Israeli directives continued to evolve to address the changing effects, we returned temporarily to the two-shift work day schedule and to again encourage employees that are able to work from home to do so for parts of September 2020.

We will continue to evaluate the impact of the COVID-19 pandemic on our business as we learn more and the impact of COVID-19 on our industry becomes more clear. We intend to continuously assess the impact of COVID-19 on our trials, expected timelines and costs.

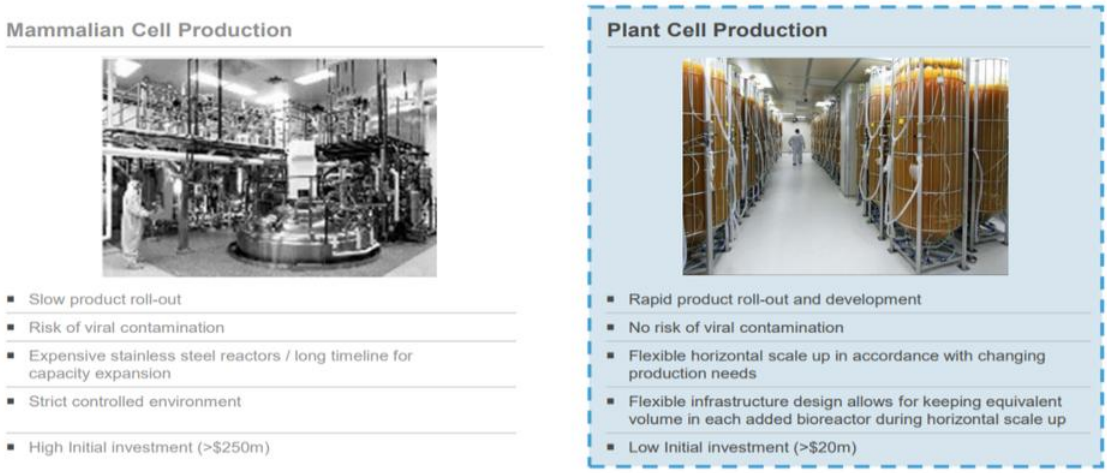
ProCellEx: Our Proprietary Protein Expression System

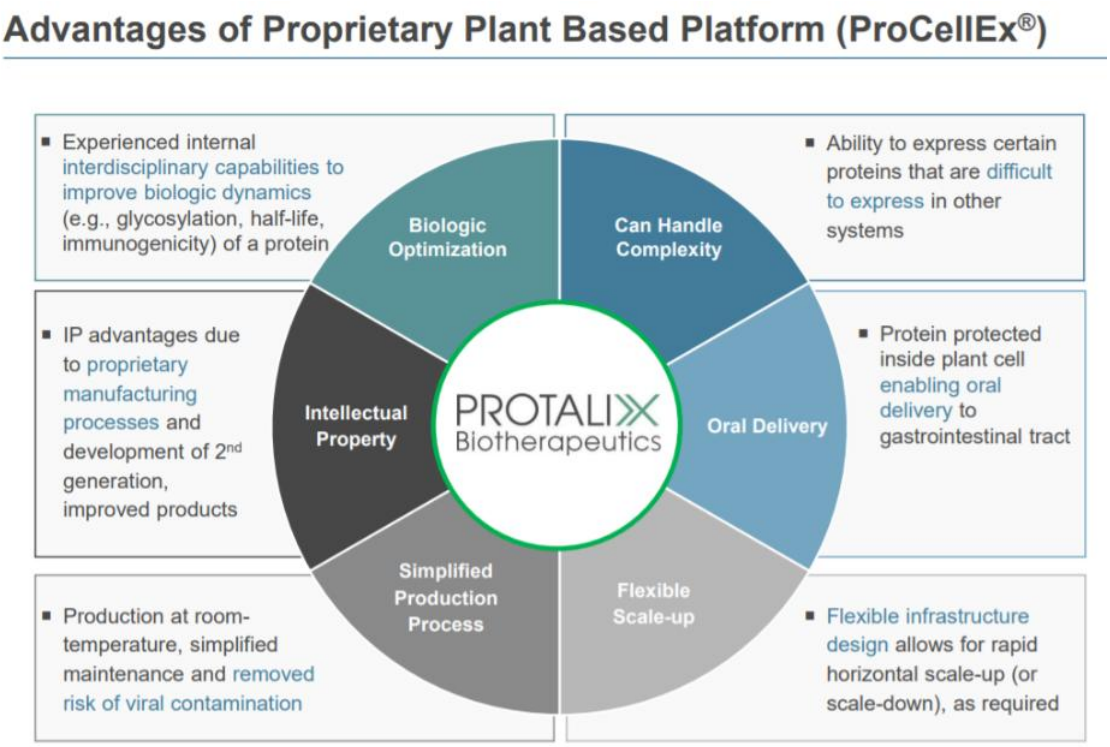
- ProCellEx is our proprietary platform used to produce and manufacture recombinant proteins through plant cell cultures in suspension. ProCellEx consists of a comprehensive set of proprietary technologies and capabilities, including the use of advanced genetic engineering and plant cell culture technology, enabling us to produce complex, proprietary, and biologically equivalent proteins for a variety of human diseases. Our protein expression system facilitates the creation and selection of high-expressing, genetically-stable cell lines capable of expressing recombinant proteins.

- Our ProCellEx technology allows for many unique advantages, including: biologic optimization; an ability to handle complex protein expressions; the potential for oral delivery of proteins; flexible manufacturing with improvements through efficiencies, enhancements and/or rapid horizontal scale-ups; a simplified production process; elimination of the risk of viral contaminations from mammalian components; and intellectual property advantages.

- 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 α-Galactosidase-A protein under development for the treatment of Fabry disease. Fabry disease is a serious life-threatening rare genetic disorder. Fabry patients lack the lysosomal enzyme, α-galactosidase-A leading to the progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide (Gb_3) in blood vessel walls throughout their body. The abnormal storage of Gb_3 increases with time and, as a result, Gb_3 accumulates, primarily in the blood and in the blood vessel walls. The accumulation leads to a narrowing of the blood vessels, which in turn leads to decreased blood flow and tissue nourishment. The ultimate consequences of Gb_3 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. Fabry disease occurs in one person per 40,000 to 60,000 males. The global market for Fabry disease was approximately $1.7 billion in 2019 (Global Data) and continues to grow at a CAGR of approximately 10% (Data Bridge Market Research).

On August 11, 2020, we, together with Chiesi, announced that the FDA had accepted the BLA for PRX-102, and granted Priority Review designation for PRX-102, for the proposed treatment of adult patients with Fabry disease. The FDA set an action date of January 27, 2021, under the Prescription Drug User Fee Act (PDUFA). The FDA also indicated in the BLA filing communication letter that it is not currently planning to hold an advisory committee meeting to discuss the application.

Priority Review is granted to therapies that the FDA determines have the potential to provide significant improvements in the treatment, diagnosis or prevention of serious conditions. This designation shortens the FDA review period following the acceptance of the BLA to six months compared to 10 months under standard review.

The BLA submission includes a comprehensive set of preclinical, clinical and manufacturing data compiled from our completed phase I/II clinical trial of PRX-102, including the related extension study succeeding our phase I/II clinical trial, interim clinical data from our phase III *BRIDGE* switch-over study and safety data from our on-going clinical studies of PRX-102 in patients receiving 1 mg/kg every other week.

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 for 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. Patients that completed the phase I/II clinical trial were offered the opportunity to continue PRX-102 treatment as part of a long-term extension study. In the phase III clinical program, we are studying two alternative doses and regimens for PRX-102; 1 mg/kg every two weeks, with the potential for improved efficacy and safety offering a potential alternative to existing enzyme replacement therapies, and 2 mg/kg every four weeks, which has the potential to lower treatment burden versus existing treatments and potentially provide a better quality of life for a subset of Fabry patients. Enrolment has been completed in each of the *BALANCE* and *BRIGHT* Studies. Topline results from the *BRIDGE* study were released in May 2020. The last patient/last visit in the *BRIGHT* study was in July 2020 and the treatment period of the study has been completed. We expect to announce topline data from this study by the end of the first quarter, 2021.

Phase III BALANCE Study

The phase III *BALANCE* clinical trial of PRX-102 for the treatment of Fabry disease, or the *BALANCE* Study, is a 24-month, randomized, double blind, active control study of PRX-102 in Fabry patients with impaired renal function. We have completed enrollment of 78 patients in the trial, which 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 Fabrazyme infused once every two weeks. Patients previously treated with Fabrazyme for approximately one year and on a stable dose for at least six months were screened and then randomized on a 2:1 ratio to 1 mg/kg of PRX-102 or 1 mg/kg of Fabrazyme. Randomization is being stratified by urinary protein to creatinine ratio (UPCR) of $<$ or $\geq$ 1 g/g by spot urine sample. The study was designed such that no more than 50% of the patients enrolled in the study would be female.

The primary endpoint for the *BALANCE* Study is the comparison in the annualized rate of decline of eGFR slope between Fabrazyme and PRX-102. eGFR is considered a clinically valuable, reliable and accepted test to measure the level of kidney function and stage of kidney disease. Additional parameters being evaluated include: cardiac assessment, lyso-Gb_3 (a biomarker for monitoring Fabry patients status), pain, quality of life, immunogenicity, Fabry clinical events, pharmacokinetics and other parameters. The study also evaluates the safety and tolerability of PRX-102.

We intend to conduct an interim analysis when the last enrolled patient reaches 12 months of treatment to test for non-inferiority to support anticipated regulatory filings with the EMA. Notwithstanding the interim analysis, patients enrolled in the *BALANCE* Study will continue to be treated for a total of 24 months, at which point the data will be analyzed to test for superiority in a final analysis of the study data. We expect to use the final analysis of the *BALANCE* Study to support converting the accelerated approval into a traditional approval, if the May 2020 PRX-102 BLA submission results in an approval from the FDA under the Accelerated Approval pathway.

Phase III BRIDGE Study

The *BRIDGE* Study is an open label, switch-over study designed to evaluate the safety and efficacy of 1 mg/kg of PRX-102 infused every two weeks, in up to 22 Fabry patients. The trial, which has been completed, enrolled patients previously treated with agalsidase alfa (Replagal®) for at least two years and on a stable dose for at least six months. Patients were screened and evaluated over three months while continuing Replagal treatment. Following the screening period, each patient was enrolled and switched from Replagal treatment to receive intravenous (IV) infusions of PRX-102 1 mg/kg every two weeks for 12 months. Topline results from the study were released in May 2020.

Topline results of the data generated in the *BRIDGE* Study showed significant improvement in renal function as measured by mean annualized estimated Glomerular Filtration Rate (eGFR slope) and an amelioration of the course of disease in both male and female patients who were switched from Replagal to PRX-102. Consistent with previously announced interim data, PRX-102 was found to be

well tolerated, with all adverse events being transient in nature without sequelae. Twenty-two patients were enrolled in the study; two of those patients withdrew early from the study due to hypersensitivity reaction, and 20 of the patients successfully completed the 12-month treatment duration. Eighteen of the patients who completed the study opted to roll over to a long-term extension study and continue to be treated with PRX-102.

In the study, the mean annualized eGFR slope of the study participants improved from -5.90 mL/min/1.73m^2/year while on Replagal to -1.19 mL/min/1.73m^2/year on PRX-1 PRX-10202 in all patients. Male patients improved from -6.36 mL/min/1.73m^2/year to -1.73 mL/min/1.73m^2/year and female patients improved from -5.03 mL/min/1.73m^2/year to -0.21 mL/min/1.73m^2/year.

Baseline characteristics of the patients, ranging from ages 24 to 60 years, were as follows: mean eGFR 75.87 mL/min/1.73m^2/year in males and 86.14 mL/min/1.73m^2 in females; mean residual leucocytes enzymatic activity was 4.8% of lab normal mean in males and 27.9% in females; and plasma lyso-Gb_3 mean levels were 49.7 nM and 13.8 nM in males and females, respectively. While lyso-Gb_3 levels remain slightly high, particularly within the male cohort, continuous reduction in lyso-Gb_3 levels was observed.

Data from the interim analysis of the *BRIDGE* Study was included in the PRX-102 BLA submission to the FDA under the Accelerated Approval pathway, and we anticipate that the final analysis will be used to support the filing of a Marketing Authorization Application (MAA) with the EMA.

Phase III BRIGHT Study

The phase III *BRIGHT* clinical trial of PRX-102 for the treatment of Fabry disease, or the *BRIGHT* Study, is a 12-month, open-label switch-over study designed to assess the safety, efficacy and pharmacokinetics (PK) of PRX-102 via intravenous (IV) infusions of 2 mg/kg administered every 4 weeks in up to 30 patients with Fabry disease, previously treated with an ERT (Fabrazyme or Replagal). The rationale for this open-label switch-over study is based on the enhanced pharmacokinetic (PK) profile of PRX-102. Phase 1/2 study measurements and PK projection modelling data suggest that PRX-102 2.0 mg/kg every 4 weeks may be beneficial in patients with mild to moderate Fabry disease. This treatment dose and regimen is aimed to serve as a maintenance program for Fabry patients without severe clinical symptoms and with relatively slow disease progression, with the potential to delay the risk of developing disease complications. To determine eligibility for participation in the study, candidates were screened to identify and select Fabry patients without severe clinical symptoms and with relatively slow disease progression whom, according to the evaluation of the treating physician, were candidates for the new regimen. Patients who 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. Enrollment in the *BRIGHT* study was completed in June 2019 and the treatment period was completed in July 2020.

Patients participating in the study are evaluated for various disease-related clinical symptoms and biomarkers, including their kidney disease rate of deterioration, while being treated with the 4-week dosing regimen as measured by eGFR. In addition, participating patients are evaluated to assess the safety and tolerability of PRX-102. This study analysis is descriptive in nature. In February 2019, we announced preliminary PK data from the *BRIGHT* study. The results demonstrate that PRX-102 was present and remained active in the plasma over the 4-week infusion intervals. The mean concentration of PRX-102 at day 28 was 138 ng/mL. In comparison, published data on Fabrazyme (1 mg/kg every 2 weeks) shows a mean concentration of 20 ng/mL at 10 hours post infusion. In addition, the area under the curve (AUC) for PRX-102 was measured to be approximately 2,000,000 ng hr/mL over 28 days. Based on published data, the AUC of Fabrazyme is approximately 10,000 ng hr/mL. A preliminary safety analysis of 19 patients enrolled in the *BRIGHT* study was also conducted, and indicated that PRX-102 is well tolerated. To date, substantially all of the patients who 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.

COVID-19 Impact on PRX-102 Clinical Trials

To date, the COVID-19 pandemic has had a minimal effect on the performance of the phase III clinical trials of PRX-102 as many of the patients were already treated in home care settings. In a minimal amount of cases, patients that completed a trial were not able to be transferred into an extension study due to the pandemic restrictions, and, accordingly, the main trial was prolonged for the patients to permit the continuation of treatment.

Phase I/II Study

Our clinical development activities for PRX-102 were initiated with a phase I/II clinical trial; a worldwide, multi-center, first-in-human, open-label, dose-ranging study to evaluate the safety, tolerability, PK, pharmacodynamics (PD) and efficacy parameters of PRX-102 administered by IV infusion every other week for 12 weeks to adult naïve symptomatic Fabry disease patients. Baseline

values for renal Gb_3 inclusions assessed by Barisoni lipid inclusion scoring system (BLISS), plasma Gb_3 and lyso-Gb_3 and supportive clinical data were collected at the start of treatment. The phase I/II clinical trial was completed in 2015.

Sixteen adult, naïve Fabry patients (9 male and 7 female) completed the trial, each in one of three dosing groups, 0.2 mg/kg, 1 mg/kg and 2 mg/kg. Each patient received intravenous (IV) infusions of PRX-102 every two weeks for 12 weeks, with efficacy follow-up after six-month and twelve-month periods. The majority of the patients who completed the trial opted to continue receiving PRX-102 in an open-label, up to 60-month extension study under which all patients receive 1 mg/kg of the drug, the selected dose for our *BALANCE* Study and *BRIDGE* Study.

The adult symptomatic, ERT-naïve Fabry disease patients enrolled in the phase I/II study were evaluated for Gb_3 levels in kidney biopsies and for plasma lyso-Gb_3 concentration by the quantitative BLISS methodology. Biopsies were available from 14 patients. The outcome of $\geq$ 50% reduction in the average number of Gb_3 inclusions per kidney PTC from baseline to month 6 was demonstrated in 11 of 14 (78.6%) of the patients treated with PRX-102. The overall results demonstrate that PRX-102 reaches the affected tissue and reduces kidney Gb_3 inclusions burden and lyso-Gb_3 in the circulation. A high correlation was found between the two Fabry disease biomarkers, reduction of kidney Gb_3 inclusions and the reduction of plasma lyso-Gb_3 over six months of treatment.

Data was recorded at 24 months from 11 patients who completed 12 months of the long-term open-label extension trial that succeeded the phase I/II study. 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 who could not continue to participate in a clinical study due to personal reasons.

Results have shown that lyso-Gb_3 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, was 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.

Commercialization Agreements with Chiesi Farmaceutici

We have entered into two exclusive global licensing and supply agreements for PRX-102 for the treatment of Fabry disease with Chiesi. The agreements have significant revenue potential for Protalix. Under the agreements, Protalix Ltd. has received $50.0 million in upfront payments and was entitled to development cost reimbursements of up to $45.0 million, up to more than $1.0 billion in potential milestone payments and tiered royalties of 15% - 35% (ex-US) and 15% - 40% (US).

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. was 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 additional payments of up to a maximum of $320.0 million 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. received an upfront, non-refundable, non-creditable payment of $25.0 million from Chiesi and was entitled to additional payments of up to a maximum of $20.0 million to cover development costs for PRX-102, subject to a maximum of $7.5 million per year. Protalix Ltd. is also eligible to receive additional payments of 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 BioManguinhos alfataliglicerase) through a supply and technology transfer agreement with Fiocruz, an arm of the Brazilian MoH. In 2019, we generated $9.1 million from sales of BioManguinhos alfataliglicerase to the Brazilian MoH.

Tulinercept (OPRX-106)

Tulinercept 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, tulinercept is designed to work locally in the gut, thereby 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 and may potentially reduce the safety concerns associated with currently approved therapies.

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 is our proprietary chemically-modified plant cell-expressed recombinant form of human deoxyribonuclease I (DNase I), administered through inhalation. In cystic fibrosis (CF) patients, the accumulation of thick 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 as a mucus thinning agent (mucolytic) to help with clearance from the airways 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 form of the enzyme will demonstrate significantly enhanced efficacy.

On July 23, 2020, we announced that we had entered into a non-binding term sheet with SarcoMed. The arrangement, if consummated, would relate to the development and commercialization of alidornase alfa for the treatment of Pulmonary Sarcoidosis and related diseases. On July 21, 2020, the FDA granted Orphan Drug Designation for alidornase alfa for the treatment of Sarcoidosis.

PRX-115

PRX-115 is our plant cell-expressed recombinant PEGylated Uricase (Urate Oxidase) – a chemically modified enzyme to treat Gout. The Uricase enzyme converts uric acid to allantoin, which is easily eliminated through urine. We use our proprietary plant-based system to express an optimized recombinant enzyme under development for the potential treatment of Gout which is designed to have an improved half-life, reduced immunogenicity and better efficacy.

Intellectual Property

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. As of September 30, 2020, we hold a broad portfolio of over 85 patents in Europe, the United States, Israel and additional countries worldwide, as well as over 35 pending patent applications.

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. As disclosed above, we have entered into a non-binding term sheet with SarcoMed. The arrangement, if consummated, would relate to the development and commercialization of alidornase alfa for the treatment of Pulmonary Sarcoidosis and related diseases.

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, 2019.

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.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our financial condition, liquidity, or results of operations will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international customers and markets.

Results of Operations

Three months ended September 30, 2020 compared to the three months ended September 30, 2019

Revenues from Selling Goods

We recorded revenues from selling goods of $3.3 million during the three months ended September 30, 2020, a decrease of $1.8 million, or 36%, compared to revenues of $5.1 million for the three months ended September 30, 2019. The decrease resulted primarily from a timing difference in sales to Brazil in 2020 compared to 2019, which was partially offset by an increase in sales to Pfizer Inc.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $7.5 million for the three months ended September 30, 2020, a decrease of $1.6 million, or 18%, compared to revenues of $9.1 million for the three months ended September 30, 2019. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. The decrease is primarily due to the completion of two out of the three phase III clinical trials of PRX-102 as well as lower costs related to the BALANCE Study.

Cost of Goods Sold

Cost of goods sold was $2.9 million for the three months ended September 30, 2020, a decrease of $0.3 million, or 11%, from cost of goods sold of $3.2 million for the three months ended September 30, 2019. The decrease is primarily due to a change in the cost structure as well as lower royalties paid to the Israeli Innovation Authority.

Research and Development Expenses, Net

Research and development expenses were $7.7 million for the three months ended September 30, 2020, a decrease of $2.3 million, or 23%, compared to $10.0 million of research and development expenses for the three months ended September 30, 2019. The decrease is primarily due to the completion of two out of the three phase III clinical trials of PRX-102 and reduced costs related to the *BALANCE* Study as well as a decrease in costs related to manufacturing of our drug in development as some of the manufactured drug product and related costs have been recorded as inventory.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.8 million for the three months ended September 30, 2020, an increase of $0.2 million, or 9%, compared to $2.6 million for the three months ended September 30, 2019.

Financial Expenses, Net

Financial expenses net were $1.9 million for the three months ended September 30, 2020, a decrease of $0.1 million, or 8%, compared to and for financial expenses net of $2.0 million for the three months ended September 30, 2019.

Nine months ended September 30, 2020 compared to the nine months ended September 30, 2019

Revenues from Selling Goods

We recorded revenues from selling goods of $12.0 million during the nine months ended September 30, 2020 and $12.1 million during the nine months ended September 30, 2019.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $31.4 million for the nine months ended September 30, 2020, an increase of $6.6 million, or 26%, compared to revenues from license and R&D services of $24.8 million for the nine months ended September 30, 2019. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. The increase is primarily due to revenues recognized in connection with an updated costs estimation throughout the trials until completion in the amount of $6.7 million.

Cost of Goods Sold

Cost of goods sold was $8.1 million for the nine months ended September 30, 2020, an increase of $0.2 million, or 2%, from cost of goods sold of $7.9 million for the nine months ended September 30, 2019.

Research and Development Expenses, Net

Research and development expenses were $27.2 million for the nine months ended September 30, 2020, a decrease of $7.8 million, or 22%, compared to $35.0 million of research and development expenses for the nine months ended September 30, 2019. The decrease is primarily due to the completion of two out of the three phase III clinical trials of PRX-102 and reduced costs related to the *BALANCE* Study as well as a decrease in costs related to manufacturing of our drug in development as some of the manufactured drug product and related costs have been recorded as inventory.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $8.2 million for the nine months ended September 30, 2020, an increase of $1.3 million, or 19%, compared to $6.9 million for the nine months ended September 30, 2019. The increase resulted primarily from a $1.3 million increase in share-based compensation costs.

Financial Expenses, Net

Financial expenses net were $6.8 million for the nine months ended September 30, 2020, an increase of $1.1 million, or 20%, compared to financial expenses net of $5.7 million for the nine months ended September 30, 2019. The increase resulted primarily from expenses related to our outstanding convertible notes equal to $1.3 million.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and bank deposits. At September 30, 2020, we had $13.5 million in cash and cash equivalents and $27.8 million in bank deposits. We have primarily financed our operations through equity and debt financings, business collaborations, and grants funding.

During the nine months ended September 30, 2020, we completed a private placement of common stock and warrants for net proceeds of approximately $41.3 million. In connection with the offering, we issued 17,604,423 unregistered shares of our common stock at a purchase price per share of $2.485 and warrants to purchase an additional 17,604,423 shares of common stock at an exercise price of $2.36 per share. In September 2020, we received cash proceeds of $472,000 from the exercise of 200,000 warrants.

We believe that our cash and cash equivalents and bank deposits as of September 30, 2020 are sufficient to satisfy our capital needs for at least 12 months from the date that these financial statements are issued. In addition, as of September 30, 2020, we had outstanding 2021 Notes amounting to $57.9 million which are due on November 15, 2021, unless the notes are refinanced, restructured or converted before that date.

We expect that by the maturity date of the 2021 Notes, our cash and cash equivalents and short term deposits, combined with the cash we anticipate to generate from the satisfaction of milestones under the Chiesi US Agreement and from our revenues, will be sufficient to satisfy the 2021 Notes payment. If, prior to the maturity date of the 2021 Notes, we will not have sufficient cash available to satisfy the full principal amount of the outstanding 2021 Notes, and to otherwise finance our future cash needs, our management may pursue corporate collaborations, licensing or similar arrangements, public or private equity offerings, and/or debt financings or restructuring, sell shares under our ATM Sales Agreement, and if necessary, may need to scale back operations, curtail or cease operations. Other than the ATM Sales Agreement, we 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. There is no assurance that we will be successful in obtaining the level of financing needed for our operations.

Cash Flows

Net cash used in operations was 18.6 million for the nine months ended September 30, 2020. In response to the COVID-19 pandemic, a higher number of subjects in our ongoing clinical trials opted for home care treatments over in-site treatments which resulted in an immaterial amount of additional expenses. The net loss for the nine months ended September 30, 2020 of $6.9 million was increased by a $15.1 million decrease in contracts liability and a $5.1 million increase in inventories, partially offset by an increase of $3.3 million in accounts payable and accruals, $2.5 million amortization of debt issuance costs and debt discount and a $2.1 million in share-based compensation. Net cash used in investing activities for the nine months ended September 30, 2020 was $27.5 million and

consisted primarily of an increase in bank deposits. Net cash provided by financing activities was $41.8 million resulting from our issuance of common stock and warrants on March 18, 2020.

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.

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. Our outstanding 2021 Notes are secured by 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.

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 believe that the funds currently available to us are sufficient to satisfy our capital needs for at least 12 months from the date that the financial statements are issued. In addition, the outstanding principal amount of the 2021 Notes must be satisfied by November 15, 2021, unless the notes are refinanced or converted before that date.

We may be required to raise additional capital in the future in order to develop and commercialize our product candidates and continue research and development activities, and to satisfy or refinance our outstanding 2021 Notes. Our ability to raise capital, and the amounts of necessary capital, will depend on many other factors, including:

- our efforts, combined with those of Chiesi, to commercialize PRX-102;
- our progress in commercializing BioManguinhos 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.

Currently, we do not expect the COVID-19 pandemic to have an adverse effect on our ability to raise capital if and to the extent we deem necessary.

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, 2020 and September 30, 2019.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2020 and September 30, 2019.

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 dollar. Most of our revenues and approximately 50% of our expenses and capital expenditures are incurred in 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.

Approximately 40% 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 revaluation of 1% of the NIS will affect our loss 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,
	2020	2019	2019
Average rate for period	3.479	3.589	3.565
Rate at period-end	3.441	3.482	3.456

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, 2020 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, 2019 and in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.

Risks Related to our ATM Program

The actual number of shares we will issue under the Sales Agreement, at any one time or in total, is uncertain, and sales of ATM Shares, or the perception that such sales may occur, may have an adverse effect on the market price of our Common Stock.

Throughout the term of the Sales Agreement, from time to time, we may instruct the Sales Agent to sell ATM Shares or sell ATM Shares to the Agent, subject to certain limitations in the Sales Agreement and compliance with applicable law. The number of ATM Shares that are ultimately sold by the Agent upon our instructions will fluctuate based on the market price of our Common Stock during the applicable sales period and the limits set forth in our instructions. Accordingly, it is not possible at this stage to predict the number of shares that will be ultimately issued, if any. Accordingly, there is no certainty that gross proceeds of $30.0 million, or any proceeds, will be raised under the Sales Agreement. The issuance and sale from time to time of new shares of Common Stock under the ATM program, or the perception that such sales may occur, may have an adverse the effect on the market price of our Common Stock. In addition, we may issue additional shares of our Common Stock in subsequent public offerings or private placements. Any issuance of new shares of our Common Stock may be dilutive to our existing stockholders.

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

On September 14, 2020, we issued 200,000 shares of Common Stock in connection with the cash exercise of a warrant issued on March 18, 2020. Except for the foregoing, there were no unregistered sales of equity securities during the three months ended September 30, 2020.

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	
1.1	ATM Equity Offering℠ Sales Agreement dated October 1, 2020 between the Company and BofA Securities, Inc.	8-K	001-33357	1.1	October 1, 2020	
3.1	Certificate of Incorporation of the Company	8-K	001-33357	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	Third Amendment to Certificate of Incorporation of the Company	8-K	001-33357	3.1	December 19, 2019	
3.5	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	
4.7	Form of Warrant	8-K	001-33357	4.1	March 12, 2020	
4.8	Form of Stock Option Agreement (Executives)	10-Q	001-33357	4.8	August 10, 2020	
4.9	Form of Stock Option Agreement (Standard)	10-Q	001-33357	4.9	August 10, 2020	
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 Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	COVER PAGE INTERACTIVE DATA FILE (formatted as Inline XBRL and contained in Exhibit 101).	

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: October 29, 2020

By: /s/ Dror Bashan

Dror Bashan
President and Chief Executive Officer
(Principal Executive Officer)

Date: October 29, 2020

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: October 29, 2020

/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: October 29, 2020

/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, 2020 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: October 29, 2020

/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, 2020 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: October 29, 2020

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