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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 March 31, 2021

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 University Plaza, Suite 100, Hackensack, NJ	**07601**
(Address of principal executive offices)	**(Zip Code)**

(201)-696-9345
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

On May 10, 2021, approximately 45,382,831 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)

	March 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,830	$ 18,265
Short-term bank deposits	50,600	20,280
Accounts receivable – Trade	4,599	2,000
Other assets	1,754	2,096
Inventories	13,915	13,082
Total current assets	$ 90,698	$ 55,723
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,776	$ 1,799
Property and equipment, net	4,828	4,845
Operating lease right of use assets	5,490	5,567
Total assets	$ 102,792	$ 67,934
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,376	$ 7,221
Other	15,167	13,926
Operating lease liabilities	1,386	1,420
Contracts liability	2,560	5,394
Convertible notes	55,372	54,427
Promissory note		4,086
Total current liabilities	$ 80,861	$ 86,474
LONG TERM LIABILITIES:		
Contracts liability	858	1,716
Liability for employee rights upon retirement	2,224	2,263
Operating lease liabilities	4,319	4,467
Other long term liabilities	26	51
Total long term liabilities	$ 7,427	$ 8,497
Total liabilities	$ 88,288	$ 94,971
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)	14,504	(27,037)
Total liabilities and stockholders' equity (net of capital deficiency)	$ 102,792	$ 67,934

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

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

	Three Months Ended	
	March 31, 2021	March 31, 2020
REVENUES FROM SELLING GOODS	$ 4,511	$ 5,031
REVENUES FROM LICENSE AND R&D SERVICES	6,809	16,615
TOTAL REVENUE	11,320	21,646
COST OF GOODS SOLD (1)	(4,765)	(3,426)
RESEARCH AND DEVELOPMENT EXPENSES, NET (2)	(7,122)	(10,340)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(3,138)	(3,187)
OPERATING INCOME (LOSS)	(3,705)	4,693
FINANCIAL EXPENSES	(2,156)	(3,229)
FINANCIAL INCOME	335	203
FINANCIAL EXPENSES – NET	(1,821)	(3,026)
OTHER INCOME	51	
NET INCOME (LOSS) FOR THE PERIOD	$ (5,475)	$ 1,667
EARNINGS (LOSS) PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.14)	$ 0.10
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE – BASIC AND DILUTED	39,933,972	17,381,074
(1) Includes share-based compensation	$ 109	$
(2) Includes share-based compensation	$ 210	$ 78
(3) Includes share-based compensation	$ 497	$ 353

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

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)
(U.S. dollars in thousands, except share data)
(Unaudited)

	Common Stock (1)	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
Balance at January 1, 2020	**14,838,213**	**$ 15**	**$ 270,492**	**$ (340,829)**	**$ (70,322)**
Changes during the three-month period ended March 31, 2020:					
Issuance of common stock and warrants, net of issuance cost	17,604,423	18	41,325		41,343
Note receivable from issuance of common stock and warrants			(4,000)		(4,000)
Share-based compensation			431		431
Net income for the period				1,667	1,667
Balance at March 31, 2020	**32,442,636**	**$ 33**	**$ 308,248**	**$ (339,162)**	**$ (30,881)**
Balance at January 1, 2021	**34,765,280**	**$ 35**	**$ 320,280**	**$ (347,352)**	**$ (27,037)**
Changes during the three-month period ended March 31, 2021:					
Issuance of common stock, net of issuance cost	8,749,999	9	37,616		37,625
Issuance of common stock under the Sales Agreement, net	1,867,552	2	8,573		8,575
Share-based compensation related to stock options			510		510
Share-based compensation related to restricted stock awards			306		306
Net loss for the period				(5,475)	(5,475)
Balance at March 31, 2021	**45,382,831**	**$ 46**	**$ 367,285**	**$ (352,827)**	**$ 14,504**

(1) Common stock, $0.001 par value; Authorized – as of March 31, 2021 and 2020 - 120,000,000 shares.

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

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

	Three Months Ended	
	March 31, 2021	March 31, 2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ (5,475)	$ 1,667
Adjustments required to reconcile net income (loss) to net cash used in operating activities:		
Share-based compensation	816	431
Depreciation	286	376
Financial income, net (mainly exchange differences)	(168)	(241)
Changes in accrued liability for employee rights upon retirement	42	44
Loss (gain) on amounts funded in respect of employee rights upon retirement	(14)	59
Gain on sale of fixed assets	(51)	
Amortization of debt issuance costs and debt discount	945	820
Changes in operating assets and liabilities:		
Decrease in contracts liability (including non-current portion)	(3,692)	(7,171)
Increase in accounts receivable and other assets	(2,282)	(4,091)
Changes in right of use assets	42	10
Increase in inventories	(833)	(1,333)
Increase in accounts payable and accruals	575	2,611
Decrease in other long term liabilities	(25)	(299)
Net cash used in operating activities	$ (9,834)	$ (7,117)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of bank deposits	$ (37,835)	$ (35,000)
Proceeds from sale of short-term deposits	7,500	
Purchase of property and equipment	(386)	(66)
Proceeds from sale of property and equipment	53	
Decrease in restricted deposit	12	22
Amounts funded in respect of employee rights upon retirement, net	(28)	(35)
Net cash used in investing activities	$ (30,684)	$ (35,079)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net payment for promissory note	$ (4,086)	
Proceeds from issuance of common stock and warrants, net	37,625	$ 38,607
Proceeds from issuance of common stock under the Sales Agreement, net	8,575	
Net cash provided by financing activities	$ 42,114	$ 38,607
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (31)	$ (37)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,565	(3,626)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	18,265	17,792
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 19,830	$ 14,166

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

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

(Continued) – 2

	Three Months Ended	
	March 31, 2021	March 31, 2020
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 202	$ 147
Right of use assets obtained in exchange for new operating lease liabilities	$ 122	$ 233
Note receivable from issuance of common stock and warrants, net of issuance cost		$ 2,736
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest received	$ 136	

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 BLA for 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, which was subsequently accepted by the FDA and granted Priority Review designation. The FDA also indicated in its BLA filing communication letter that it did not plan to hold an advisory committee meeting to discuss the application. On April 28, 2021, the Company, together with its development and commercialization partner for PRX-102, Chiesi Farmaceutici S.p.A. ("Chiesi"), announced that they received a Complete Response Letter (CRL) from the FDA regarding the BLA. The CRL did not report any concerns relating to the potential safety or efficacy of PRX-102 in the submitted data package.

In the CRL, the FDA noted that an inspection of Protalix's manufacturing facility in Carmiel, Israel, including the FDA's subsequent assessment of any related FDA findings, is required before the FDA can approve the BLA. Due to travel restrictions, the FDA was unable to conduct the required inspection during the review cycle. The FDA explained in the letter that it will continue to monitor the public health situation as well as travel restrictions, and is actively working to define an approach for scheduling outstanding inspections. With respect to the third-party facility in Europe at which fill and finish processes are performed for PRX-102, due to the novel coronavirus disease, or COVID-19, the FDA reviewed records under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act in lieu of a pre-licensing inspection. In the CRL, the FDA stated that it will communicate remaining issues to the facility in order to seek prompt resolution of any pending items.

In addition to the foregoing, in the CRL, the FDA noted that agalsidase beta (Fabrazyme®), a therapy used to treat Fabry patients, was recently converted to full approval which must be addressed in the context of any potential resubmission seeking accelerated approval of PRX-102. The Company intends to work collaboratively with the FDA to identify the most expeditious pathway to approval, including accelerated approval. Protalix remains confident that it will be able to work with the FDA to resolve these issues and provide a new, alternative drug to Fabry patients. The Company intends to request a Type-A meeting with the FDA, and will provide further updates on next steps after this meeting; however, the Company cannot anticipate the timing of such a meeting nor the additional steps that may be required in connection with any potential resubmission.

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, which is subject to an exclusive worldwide license agreement with SarcoMed USA, Inc. ("SarcoMed") for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery;

(2) PRX-115, the Company's plant cell-expressed recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme to treat refractory gout; and

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

(3) PRX-119, the Company's plant cell-expressed PEGylated recombinant human DNase I product candidate being designed to elongate half-life in the circulation for NETs-related diseases.

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 February 10, 2021, the Company entered into an exclusive worldwide license agreement with SarcoMed with respect to PRX-110 for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery. Under the terms of the agreement, SarcoMed will be responsible for the identification and selection of pharmaceutical candidates under the license, and the clinical research and development of such candidates. The Company is entitled to an initial cash payment of $3.5 million, subject to certain conditions, and to additional regulatory and commercial milestone payments and tiered royalties on net sales of products that are commercialized under the license agreement. In addition to the foregoing, the parties agreed to commence negotiation of clinical and commercial supply agreements for alidornase alfa. As part of the arrangement, the parties agreed to negotiate and sign a supply agreement within 60 days of the execution of the license agreement, and SarcoMed has the right to terminate the license agreement if the parties do not successfully do so.

On February 17, 2021, the Company issued and sold 8,749,999 shares of its common stock, par value $0.001 per share (the "Common Stock"), in an underwritten public offering raising gross proceeds of approximately $40.2 million at a price equal to $4.60 per share, before deducting the underwriting discount and estimated expenses of the offering. BofA Securities, Inc. ("BofA Securities") acted as book-running manager for the offering with Oppenheimer & Co. acting as co-manager.

On March 29, 2021, the Company made a payment of approximately $4.0 million to Pfizer Inc. ("Pfizer") satisfying the outstanding promissory note payable to Pfizer in full.

On October 1, 2020, the Company entered into an ATM Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with BofA Securities 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 Common Stock having an aggregate offering price of up to $30.0 million (the "ATM Shares"). During 2021 to date, the Company sold 1,867,552 ATM Shares for gross proceeds of $8.8 million. As of the issuance date of the financial statements, the Company has the right to raise an additional $16.2 million of capital under the Sales 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%

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(Unaudited)

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.

Subsequent to March 31, 2021, the Company signed a binding term sheet with Chiesi, pursuant to which the parties reached certain agreements including a $10.0 million payment by Chiesi prior to June 30, 2021 in exchange for the reduction of a longer-term regulatory milestone payment set forth in the Chiesi EX-US Agreement by $25.0 million. All other regulatory and commercial milestone payments remain unchanged.

Since its approval by the FDA, taliglucerase alfa has been marketed by 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.

COVID-19, which was declared by the World Health Organization to be a global pandemic on March 11, 2020, has had numerous adverse effects on the global economy. To date, the Company's clinical trials have not been adversely affected by COVID-19, although certain practices the Company has adopted in its offices and facilities in an effort to promote social distancing have resulted in minor delays in the performance of administrative activities outside of the clinical programs. We continue to face uncertainty as to the degree and duration of that impact going forward. The Company does not know the length of time that the pandemic and related disruptions will continue, the impact of governmental regulations or easement of regulations in response to the strengthening or weakening of the pandemic, or the degree of overall potentially permanent changes in consumer behavior that may be caused by the pandemic.

The Company believes that its cash and cash equivalents and bank deposits as of March 31, 2021 are sufficient to satisfy the Company's capital needs for at least 12 months from the date that these financial statements are issued. The Company expects that such cash and cash equivalents and bank deposits will be sufficient to satisfy the full payment of the principal amount of the Company's 7.50% convertible secured promissory notes due November 15, 2021 equal to $57.9 million, unless the notes are refinanced, restructured or converted before that date.

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.

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

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, 2020, filed by the Company with the U.S. Securities and Exchange Commission (the "Commission"). The comparative balance sheet at December 31, 2020 has been derived from the audited financial statements at that date. There have been no material changes in our significant accounting policies as described in our consolidated financial statements for the year ended December 31, 2020.

c. Earnings (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 10,694,517 and 26,769,693 shares of Common Stock underlying outstanding options and shares of Common Stock issuable upon conversion of outstanding convertible notes and outstanding warrants for the three months ended March 31, 2020 and 2021, respectively, because their effect would be anti-dilutive.

d. Revenue recognition

The Company accounts for revenue pursuant to 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.

PROTALIX BIOTHERAPEUTICS, INC.
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(Unaudited)

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.

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.

NOTE 2 - INVENTORIES

Inventories at March 31, 2021 and December 31, 2020 consisted of the following:

(U.S. dollars in thousands)	March 31, 2021	December 31, 2020
Raw materials	$ 3,427	$ 3,347
Work in progress	2,273	2,887
Finished goods	8,215	6,848
Total inventory	$ 13,915	$ 13,082

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.

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

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

As of March 31, 2021, the carrying amounts of short-term deposits approximate their fair values due to the stated interest rates, which approximate market rates.

The fair value of the $57.9 million aggregate principal amount of the Company's outstanding 7.50% 2021 Notes as of March 31, 2021 is approximately $59.8 million based on a Level 3 measurement.

The Company prepared a valuation of the fair value of the Company's outstanding 2021 Notes (a Level 3 valuation) as of March 31, 2021. 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)	4.46
Expected term	0.63
Risk free rate	0.05 %
Volatility	71.89 %
Yield	11.54 %

NOTE 4 – REVENUES

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

(U.S. dollars in thousands)	Three Months Ended March 31, 2021	2020
Pfizer	$ 4,511	$ 2,016
Brazil	$ —	$ 3,015
Total revenues from selling goods	$ 4,511	$ 5,031
Revenues from license and R&D services	$ 6,809	$ 16,615

During the three months ended March 31, 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 connection with the Chiesi Agreements.

NOTE 5 – 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 receives any milestone payment from Chiesi, if at all, subject to certain conditions and exceptions. The amendment also required that the Company make a payment of $430,000 to Pfizer. The payment was creditable against the principal amount of the note, in whole or in part, if the Company was to satisfy the note in full on or prior to September 30, 2021, depending on the date the note is satisfied. On March 29, 2021, the Company made a payment of approximately $4.0 million to Pfizer satisfying the note in full.

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS SUMMARY

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, 2020. 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 this Quarterly Report on Form 10-Q.

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

- risks related to the timing and progress of the preparation of an updated BLA addressing the CRL;
- risks related to the timing, progress and likelihood of final approval by the FDA of a resubmitted BLA for PRX-102 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;
- 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 ability to make required payments under our outstanding convertible notes or any other indebtedness as they come due and our ability to obtain additional financing and raise capital as necessary should the regulatory approval process become more extended;
- risks associated with the COVID-19 outbreak, which may adversely impact our business, preclinical studies and clinical trials;
- 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 changes to interim, topline or preliminary data from clinical trials that we announce or publish;
- risks related to any transactions we may effect in the public or private equity markets to raise capital to finance future research and development activities, general and administrative expenses and working capital;

- risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector;
- 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;
- 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;
- 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 May 13, 2021, we signed a binding term sheet with Chiesi pursuant to which we amended the Chiesi Agreements in order to provide us with near-term capital. Chiesi agreed to make a $10.0 million milestone payment to us before the end of the second quarter in exchange for a $25.0 million reduction in a longer term regulatory milestone payment in the Chiesi EX-US Agreement. All other regulatory and commercial milestone payments remain unchanged. We also agreed to negotiate certain manufacturing related matters.
- On April 28, 2021, we, together Chiesi, announced the receipt from the FDA of a CRL in response to the PRX-102 BLA.
- On February 23, 2021, we, together with Chiesi, announced positive topline results from our phase III *BRIGHT* clinical trial of PRX-102 for the treatment of Fabry disease, or the *BRIGHT* study, designed to evaluate the safety, efficacy and pharmacokinetics of PRX-102 treatment, 2 mg/kg every four weeks, in up to 30 patients with Fabry disease previously treated with a commercially available ERT (agalsidase alfa – Replagal® or agalsidase beta – Fabrazyme®).
- On February 18, 2021, we announced the closing of a public offering of our common stock raising gross proceeds of approximately $40.2 million at a price equal to $4.60 per share, before deducting the underwriting discount and estimated expenses of the offering.
- On February 11, 2021, we announced an exclusive worldwide license agreement with SarcoMed for PRX-110 for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery.

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. Our facility currently operates on a regular schedule with adherence to local guidelines.

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.

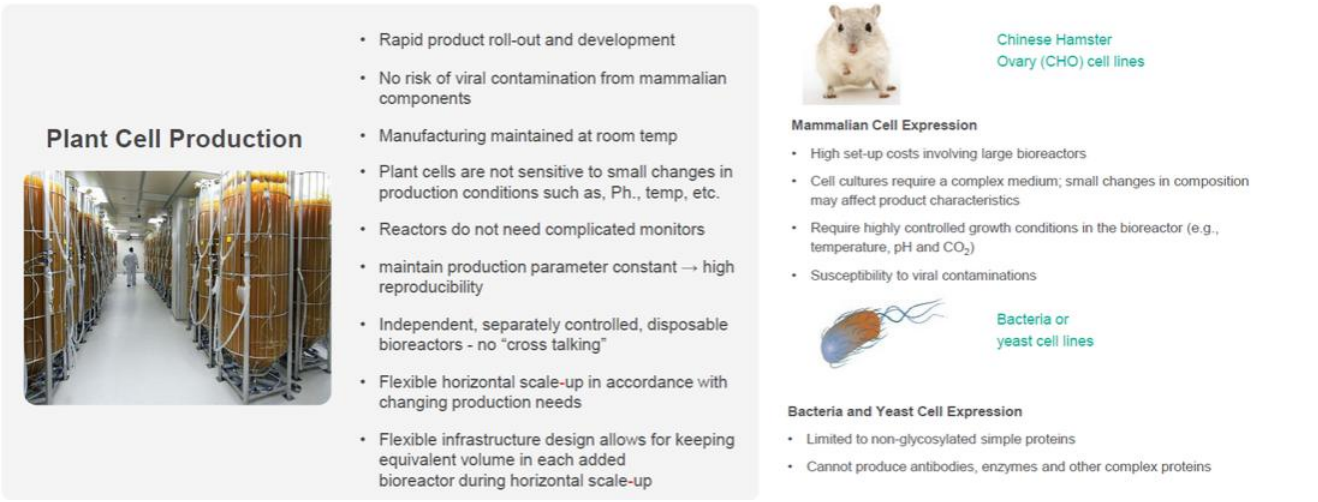
ProCellEx: Our Proprietary Protein Expression System

- ProCellEx is our proprietary platform used to produce and manufacture recombinant proteins through plant cell-based expressions 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; 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.

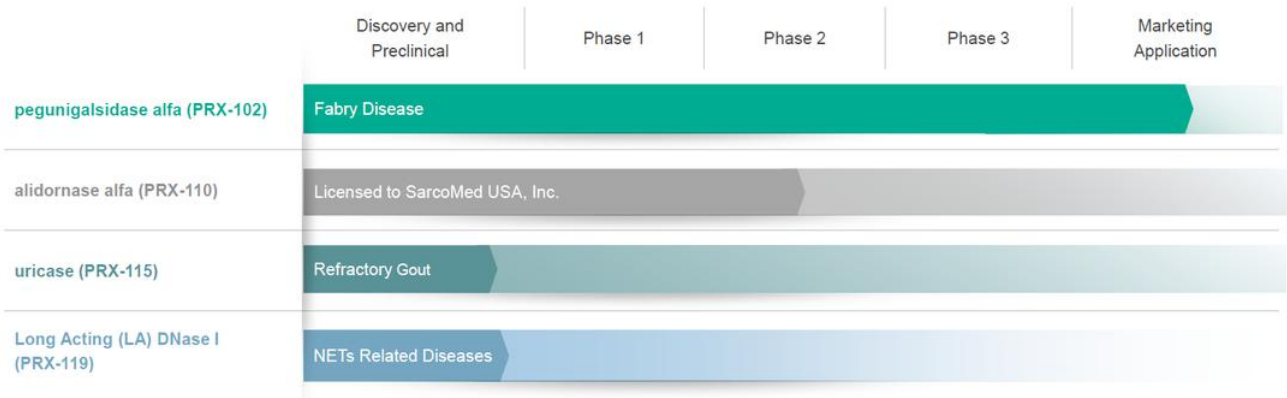
Plant Cell Production Advantages



Plant Cell in Suspension Expression System for Therapeutic Proteins Development and Industrial Production: Executive Summary

Cell lines and Genetic Engineering	Unique genetic engineering tools used for producing improved tobacco plant cell lines and plant viral based constructs achieving optimized therapeutic proteins profiles and reducing safety risks
Biologic Optimization	Experienced internal interdisciplinary capabilities (e.g., genetic engineering and chemical modification) to improve biologic attributes: consistent glycosylation, elongated half-life, reduced immunogenicity, enhanced protein stability/activity
Intellectual Property	IP advantages due to proprietary manufacturing processes and development of 2nd generation improved products, related to Composition of Matter protection on the one hand and FTO on the other hand
Simplified and consistent Production Process	Production at room temperature, simplified maintenance with no risk of viral contamination from mammalian components; high batch to batch reproducibility
Can Handle Complexity	Ability to express certain proteins that are difficult to express in other systems
GMP compliance	Implementation of applicable regulatory requirements known to the Biotech industry
Flexible Scale-Up	Flexible infrastructure design allows for rapid horizontal scale-up (or scale-down)

Product Pipeline



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

PRX-102 is our lead product candidate and we expect it to be the primary subject of our development efforts in the short-term. It is our proprietary, investigational, plant cell culture expressed enzyme, and a chemically modified stabilized version of, the recombinant α-Galactosidase-A protein, a lysosomal enzyme, under development for the treatment of Fabry disease. Fabry disease is a serious life-threatening rare genetic disorder. Fabry patients lack α-galactosidase-A resulting in the progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide, or 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 is forecasted to be approximately $1.9 billion in 2021 (Global Data) and to continue to grow at a CAGR of approximately 9.5% (Global Data).

A BLA for PRX-102 for the treatment of adult patients with Fabry disease was submitted to the FDA on May 27, 2020 under the FDA's Accelerated Approval pathway, which was subsequently accepted by the FDA and granted Priority Review designation. As discussed above, on April 28, 2021, we, together with Chiesi, announced the receipt of a CRL from the FDA regarding the BLA.

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.

The CRL did not report any concerns relating to the potential safety or efficacy of PRX-102 in the submitted data package.

In the CRL, the FDA noted that an inspection of Protalix's manufacturing facility in Carmiel, Israel, including a subsequent assessment of any related FDA findings, is required before the FDA can approve the BLA. Due to travel restrictions, the FDA was unable to conduct the required inspection during the review cycle. The FDA explained in the letter that it will continue to monitor the public health situation as well as travel restrictions, and is actively working to define an approach for scheduling outstanding inspections. With respect to the third-party facility in Europe at which fill and finish processes are performed for PRX-102, due to COVID-19, the FDA reviewed records under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act in lieu of a pre-licensing inspection. In the CRL, the FDA stated that it will communicate remaining issues to the facility in order to seek prompt resolution of any pending items.

In addition to the foregoing, in the CRL, the FDA noted that Fabrazyme, a therapy used to treat Fabry patients, was recently converted to full approval which must be addressed in the context of any potential resubmission seeking accelerated approval of PRX-102. Protalix intends to work collaboratively with the agency to identify the most expeditious pathway to approval, including accelerated approval. We remain confident that we will be able to work with the FDA to resolve these issues and provide a new, alternative drug to Fabry patients. We intend to request a Type-A meeting with the FDA, and will provide further updates on next steps after the meeting; however, we cannot anticipate the timing of such a meeting nor the additional steps that may be required in connection with any potential resubmission.

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. Enrollment has been completed in all three 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. Final results from the *BRIDGE* study were released in December 2020 and topline results from the *BRIGHT* study were released in February 2021. We expect to announce interim data from the *BALANCE* study by the end of the first half of 2021.

In February 2020, we, together with Chiesi, announced an agreement with the FDA for the Initial Pediatric Study Plan (iPSP) for PRX-102. The joint announcement was made after completion of discussions with the FDA and receipt of confirmation from the FDA

in an official “Agreement Letter” which outlines an agreed-upon approach to evaluate the safety and efficacy of PRX-102 in pediatric Fabry patients in a clinical trial to be performed by Chiesi with our collaborative efforts.

Phase III BALANCE Study

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. Approximately 40% of the enrolled patients were 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 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 during therapy), pain, quality of life, immunogenicity, Fabry clinical events and pharmacokinetic and other parameters. The study also evaluates the safety and tolerability of PRX-102.

We intend to conduct an interim analysis when the last patient reaches 12 months of treatment to test for non-inferiority to support anticipated regulatory filings with the EMA. 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. If the anticipated BLA filing results in an approval from the FDA under the Accelerated Approval pathway, this analysis will also be used to support converting the accelerated approval into a full approval. We anticipate announcing interim results from our *BALANCE* study in the first half of 2021.

Phase III BRIDGE Study

The *BRIDGE* study was a 12-month open-label, single arm switch-over study evaluating the safety and efficacy of pegunigalsidase alfa, 1 mg/kg infused every two weeks, in up to 22 Fabry patients. The trial, which is was completed in December 2019, enrolled patients then being treated with agalsidase alfa, marketed by Takeda Pharmaceutical Company Limited (formerly Shire Plc) as 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.

Final results of the data generated in the study showed substantial improvement in renal function as measured by mean annualized estimated Glomerular Filtration Rate, or eGFR, slope in both male and female patients who were switched from agalsidase alfa to PRX-102. Twenty of 22 patients 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 agalsidase alfa to -1.19 mL/min/1.73m^2/year on PRX-102 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. Following the switch to PRX-102, there was a decrease in patients with progressing or fast progressing kidney disease, and most patients achieved a stable status post-switch.

PRX-102 was well-tolerated in the study, with all adverse events being transient in nature without sequelae. Of the 22 patients enrolled in the *BRIDGE* study, the majority of treatment emergent adverse events were mild or moderate in severity, with two patients (9.1%) withdrawing from the therapy due to hypersensitivity reaction that was resolved. The most common moderate treatment emergent adverse events were nasopharyngitis, headache and dyspnea.

An immunogenicity assessment indicated that four out of 20 patients (20%) developed persistent antidrug antibodies over the course of the study, of which two had neutralizing activity.

Baseline characteristics of the 20 patients that completed the study, ranging from ages 28 to 60 years, were as follows: mean eGFR 75.87 mL/min/1.73m^2 in males, and 86.14 mL/min/1.73m^2 in females and plasma lyso-Gb_3 were 51.81 nM and 13.81 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 of 19.55 nM (32.35%) in males and 4.57 nM (29.81%) in females.

Data from the interim analysis of the *BRIDGE* study, which were first announced in February 2020, were used to support the PRX-102 BLA filing with the FDA, and we anticipate that the final analysis will be used to support a Marketing Authorization Application, or 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, was a 12-month, open-label, switch-over study designed to evaluate the safety, efficacy and pharmacokinetics of PRX-102 via IV infusions of 2 mg/kg administered every 4 weeks. The trial, which was completed in June 2020, enrolled up to 30 patients with Fabry disease previously treated with a commercially available ERT (Fabrazyme or Replagal), for at least three years and on a stable dose administered every two weeks. To determine eligibility for participation in the study, candidates were screened to identify and select Fabry patients with stable kidney disease. Patients who matched the criteria were enrolled in the study and switched from their current treatment of IV infusions every 2 weeks to 2 mg/kg of PRX-102 every 4 weeks for 12 months. Patients participating in the study were evaluated, among other disease parameters, to determine if their kidney disease had not further deteriorated while being treated with the 4-week dosing regimen as measured by eGFR and Lyso-Gb_3, as well as other parameters. In addition, participating patients were evaluated to assess the safety and tolerability of PRX-102.

We announced topline results in February 2021. The topline results indicate that 2 mg/kg of PRX-102 administered by intravenous infusion every four weeks was found to be well tolerated among treated patients, and stable clinical presentation was maintained in adult Fabry patients. No new patients developed treatment-induced anti-drug antibodies, or ADA, following the switch to PRX-102 treatment.

The *BRIGHT* study enrolled 24 adult males and 6 adult females. The most common Fabry disease symptoms were acroparesthesia, heat intolerance, angiokeratomas and hypohydrosis. All 30 patients received at least one dose of PRX-102, and 29 patients (mean [SD] age was 40.5 [11.3] years, ranging from 19 to 58 years) completed the 12-month study. Of these 29 patients, 28 received the intended regimen of 2 mg/kg every four weeks throughout the study, while one patient was switched to PRX-102 1 mg/kg every two weeks per protocol. One patient withdrew from the study after the first infusion due to a traffic accident.

Following screening, patients were enrolled and switched from their then current ERT to IV infusions of 2 mg/kg of PRX-102 every four weeks for 52 weeks (a total of 14 infusions). First infusions of PRX-102 were administered under controlled conditions at the investigation site. Based on the protocol-specified criteria, patients were able to receive their PRX-102 infusions at a home care setup once the Investigator and Sponsor Medical Monitor agreed that it was safe to do so. Safety and efficacy exploratory endpoints were assessed throughout the 52-week study.

Study outcome measures showed plasma lyso-Gb_3 concentrations remained stable during the study with a mean change of 3.01 nM from baseline (19.36 nM) to Week 52 (22.23 nM). Mean absolute change of eGFR values were stable during the 52-week treatment period, with a mean change from baseline of -1.27 mL/min/1.73m^2.

Following a survey of participants using the Quality of Life EQ-5D-5L questionnaire, responses indicate that patient perception of their own health remained high and stable throughout the 52-week study duration, with overall health mean (SE) scores of 78.3 (3.1) and 82.1 (2.9) at baseline and Week 52, respectively, in a 0 to 100 scale. Using the short-form Brief Pain Inventory, or BPI, questionnaire, approximately 75% of study participants had an improvement or no change in average pain severity at Week 52 (compared to baseline). The short-form BPI interference items also remained stable during the study. Pain-related results indicate that there was no increase and/or relapse in pain. No Fabry clinical events were reported during the study.

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 phase I/II clinical trial of PRX-102, which we completed in 2015, was a worldwide, multi-center, open-label, dose ranging study designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and efficacy parameters of PRX-102 in adult Fabry patients. 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 IV infusions of PRX-102 every two weeks for 12 weeks, with efficacy follow-up after six-month and twelve-month periods. A majority of the patients who completed the trial opted to continue receiving PRX-102 in an open-label, 60-month extension study under which all patients were switched to receive 1 mg/kg of the drug, the selected dose for our *BALANCE* and *BRIDGE* studies of PRX-102.

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 ≥ 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 relocated to a location where treatment was not available under the clinical study.

Results show 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, or 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). To date, Protalix Ltd. has received the complete amount of development costs to which it is entitled under the two Agreements.

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 is also required to 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.

On May 13, 2021, we signed a binding term sheet with Chiesi pursuant to which we amended the Chiesi Agreements in order to provide us with near-term capital. Chiesi agreed to make a $10.0 million milestone payment to us before the end of the second quarter in exchange for a $25.0 million reduction in a longer term regulatory milestone payment in the Chiesi EX-US Agreement. All other regulatory and commercial milestone payments remain unchanged. We also agreed to negotiate certain manufacturing related matters.

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, also known as glucocerebrosidase, or GCD, deficiency, is a rare genetic autosomal recessive disorder and one of the most common Lysosomal Storage Disorders, or LSD, in the world. It is one of a group of disorders that affect specific enzymes that normally break down fatty substances for reuse in the cells. If the enzymes are missing or do not work properly, the substances can build up and become toxic. Gaucher disease occurs when a lipid called glucosylceramide accumulates in the cells of the bone marrow, lungs, spleen, liver, and sometimes the brain. Gaucher disease symptoms can include fatigue, anemia, easy bruising and bleeding, severe bone pain and easily broken bones, and distended stomach due to an enlarged spleen and thrombocytopenia. Epidemiology of Gaucher disease varies; recent literature provides that prevalence of Gaucher disease ranges from 0.70 to 1.75 per 100,000 in the general population. In people of Ashkenazi Jewish heritage, estimates of occurrence vary from approximately 1 in 400 to 1 in 850 people.

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. In a subsequent amendment, we agreed that after the completion of the first 10-year supply period, the supply term would automatically extend for a five-year period.

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 2020, we generated $8.0 million from sales of BioManguinhos alfataliglicerase to the Brazilian MoH.

Alidornase Alfa (PRX-110)

Alidornase alfa is our chemically-modified plant cell expressed recombinant human DNase I, administered via inhalation. Recombinant human DNase I enzymatically cleaves DNA but its activity is inhibited by actin, which is present in the blood and other target organs. PRX-110 is designed to be less susceptible to actin inhibition and have higher affinity to DNA, thus enhancing enzymatic activity. In-vitro studies have shown PRX-110 to have a highly improved catalytic efficiency and affinity to DNA, compared to dornase alfa (Pulmozyme®, currently the only commercially available DNase therapy), even more so in the presence of actin.

On February 10, 2021, we entered into an exclusive worldwide license agreement with SarcoMed with respect to PRX-110 for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery.

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 under development for the potential treatment of refractory gout. Gout is the most common inflammatory arthritis in the United States, affecting an estimated 9.2 million adults. Gout is caused by factors that elevate serum uric acid, or sUA, levels, which may include diet or genetic predisposition and environmental factors leading to hyperuricemia and tissue deposition of monosodium urate crystals, tophi, in joints and soft tissues, causing acute and chronic inflammation, and is characterized by recurrent flares. Gout flares lead to substantial morbidity by causing severe pain, reduced quality of life, decreased physical function, increased healthcare costs, and lost economic productivity. Furthermore, gout is strongly associated with metabolic syndrome, and may contribute to myocardial infarction, type 2 diabetes mellitus, chronic kidney disease, or CKD, and premature mortality.

Currently available urate-lowering therapies, or ULTs, can be effective in treating gout. Refractory gout patients are those whom, despite treatment with existing ULTs, have high flare frequency, consistent tophi, and the inability to maintain therapeutic goals of urate levels. An estimated approximately 2% of the gout population is considered to have chronic refractory disease and are in in need of other therapeutic options. One option may be a therapeutic use of the uricase enzyme which converts uric acid to allantoin, which is easily eliminated through urine. The uricase enzyme does not exist naturally in humans. To date, two variants of recombinant uricases are approved for marketing: (i) Krystexxa® for treatment of chronic gout refractory to conventional therapy (no longer approved in the European Union) and (ii) Elitek®, indicated for the treatment of tumor lysis syndrome but not gout. Both have a black box warning for anaphylaxis, induce strong immunogenic reactions and have other major side-effects. We use ProCellEx to express an optimized recombinant uricase enzyme under development for the potential treatment of refractory gout which we are designing to have an improved half-life, reduced immunogenicity and potentially longer term efficacy.

PRX-119

PRX-119 is our plant cell-expressed PEGylated recombinant human DNase I product candidate being designed to elongate half-life in the circulation for NETs-related diseases. NETs, Neutrophil extracellular traps, are web-like structures, released by activated neutrophils that trap and kill a variety of microorganisms. NETs are composed of DNA, histones, antimicrobial and pro-inflammatory proteins. Excessive formation or ineffective clearance of NETs can cause different pathological effects. NETs formation has been observed in various autoimmune, inflammatory and fibrotic conditions, diverse forms of thrombosis, cancer and metastasis. According to scientific literature, animal studies have demonstrated that DNase treatment reduces NETs toxicity. Our proprietary modified DNase I design for long and customized systemically circulating in the bloodstream, may potentially enable effective treatment of acute and chronic conditions.

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 March 31, 2021, we hold a broad portfolio of over 90 patents in Europe, the United States, Israel and additional countries worldwide, as well as over 35 pending patent applications.

Scientific Presentations

On February 1, 2021, Prof. Ales Linhart, M.D., Charles University, Praha, Czech Republic, a principal investigator in our pegunigalsidase alfa phase III clinical trials, delivered an oral presentation entitled “Switching from agalsidase alfa to pegunigalsidase alfa to treat patients with Fabry disease: 1 year of treatment data from BRIDGE, a phase 3 open-label study,” describing the final results of the *BRIDGE* study. The presentation was delivered at the 17th Annual WORLD*Symposium*™, a research conference dedicated to lysosomal diseases held virtually February 8-12, 2021. Dr. Linhart also made a poster presentation on the same date and on the same topic at the conference.

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 an exclusive license agreement with SarcoMed relating to the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery.

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, 2020.

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 March 31, 2021 compared to the three months ended March 31, 2020

Revenues from Selling Goods

We recorded revenues from selling goods of $4.5 million during the three months ended March 31, 2021 a decrease of $0.5 million, or 10%, compared to revenues of $5.0 million for three months ended March 31, 2020. The decrease of $3.0 million in sales to Brazil was partially offset by an increase of $2.5 million in sales to Pfizer.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $6.8 million for the three months ended March 31, 2021, a decrease of $9.8 million, or 59%, compared to revenues from license and R&D services of $16.6 million for the three months ended March 31, 2020. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. The decrease resulted primarily from revenues for the three months ended March 31, 2020 recognized in connection with an updated costs estimation throughout the trials until completion, made in 2020, in the amount of $6.7 million and from revenues recognized in connection with the progress of our clinical trials that have been completed during 2020.

Cost of Goods Sold

Cost of goods sold was $4.8 million for the three months ended March 31, 2021, an increase of $1.4 million, or 41%, from cost of goods sold of $3.4 million for the three months ended March 31, 2020. The increase in cost of goods sold was primarily the result of higher manufacturing costs.

Research and Development Expenses, Net

Research and development expenses were $7.1 million for the three months ended March 31, 2021, a decrease of $3.2 million, or 31%, compared to $10.3 million of research and development expenses for the three months ended March 31, 2020. 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.

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 $3.1 million for the three months ended March 31, 2021, a decrease of $0.1 million, or 3%, compared to $3.2 million for the three months ended March 31, 2020.

Financial Expenses, Net

Financial expenses net were $1.8 million for the three months ended March 31, 2021, a decrease of $1.2 million, or 40%, compared to financial expenses net of $3.0 million for the three months ended March 31, 2020. The decrease resulted primarily from a decrease in 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 March 31, 2021, we had $19.8 million in cash and cash equivalents and $50.6 million in short-term bank deposits. We have primarily financed our operations through equity and debt financings, business collaborations, and grants funding.

During the three months ended March 31, 2021, we raised gross proceeds equal to approximately $8.8 million from sales of common stock under our ATM program through the sale of 1,867,552 shares of our common stock. In addition, we raised gross proceeds of approximately $40.2 million from a public offering of our common stock before deducting the underwriting discount and estimated expenses of the offering. In connection with the offering, we issued 8,749,999 shares of our common stock at a purchase price per share of $4.60.

We believe that our cash and cash equivalents and bank deposits as of March 31, 2021 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 March 31, 2021, we have 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.

Cash Flows

Net cash used in operations was $9.8 million for the three months ended March 31, 2021. 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 three months ended March 31, 2021 of $5.5 million was increased by a $3.7 million decrease in contracts liability, a $2.3 million increase in accounts receivable and other assets and a $0.8 million increase in inventories, partially offset by an increase of $0.6 million in accounts payable and accruals, $0.9 million amortization of debt issuance costs and debt discount and $0.8 million in share-based compensation. Net cash used in investing activities for the three months ended March 31, 2021 was $30.7 million and consisted primarily of an increase in bank deposits. Net cash provided by financing activities was $42.1 million resulting from the sale of common stock under our ATM program and from our public offering of common stock, net of the promissory note payment.

Net cash used in operations was $7.1 million for the three months ended March 31, 2020. The net income for the three months ended March 31, 2020 of $1.7 million decreased by a $7.2 million decrease in contracts liability, a $4.1 million increase in account receivable and other assets and a $1.3 million increase in inventories, and was increased by an increase of $2.6 million in accounts payable and accruals, and by $0.8 million amortization of debt issuance costs and debt discount. Net cash used in investing activities for the three months ended March 31, 2020 was $35.0 million and consisted primarily of an increase in bank deposits. Net cash provided by financing activities was $38.6 million resulting from our issuance of common stock and warrants on March 18, 2020.

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 as we increase our research and developments efforts with respect to our product candidates given the receipt of the CRL from the FDA discussed above, we expect to incur additional expenses in connection with any resubmission. We cannot anticipate the costs or the timing of the occurrence of such costs. As well, to the extent we need to obtain additional financing in connection with this process or with any additional clinical testing that may be required, it may be more difficult for us to do so given the volatility of the price of our common stock. 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.

As discussed above, we may be required to raise additional capital to develop our product candidates and continue research and development activities. Our ability to raise capital, and the amounts of necessary capital, will depend on many other factors, including:

- our efforts, combined with those of Chiesi, to file for resubmission with the FDA and to commercialize PRX-102;
- the progress and results of our clinical trials, particularly the PRX-102 *BALANCE* study;
- our progress in commercializing BioManguinhos alfataliglicerase in Brazil;
- the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates;
- the timing and outcome of regulatory review of our product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights; and
- the costs associated with any litigation claims.

We expect to finance our future cash needs through corporate collaborations, licensing or similar arrangements, public or private equity offerings and/or debt financings. We currently do not have any commitments for future external funding, except with respect to the development-related payments and milestone payments that may become payable under the Chiesi Agreements and under our agreement with SarcoMed. In addition, our ATM program provides us with a quick and efficient manner to raise capital through the sale of shares of our common stock. To date, we have the right to raise an additional $16.2 million of capital through sales of our common stock through the ATM program.

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 three months ended March 31, 2021 and March 31, 2020.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of March 31, 2021 and March 31, 2020.

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 52% 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 43% 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:

	Three Months Ended March 31,		Year Ended December 31,
	2021	2020	2020
Average rate for period	3.268	3.504	3.442
Rate at period-end	3.334	3.565	3.215

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 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 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 March 31, 2021 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

You should carefully consider the following information about the risks described below, together with the other information contained in this Quarterly Report and in our other public filings in evaluating our business. The risk factors set forth below that are marked with an asterisk (*) did not appear as separate risk factors in, or contain changes to the similarly titled risk factor included in, Item 1A of our Annual Report. If any of the following risks actually occurs, our business, financial condition, results of operations, and future growth prospects would likely be materially and adversely affected. If any of these risks occur, the value of our common stock could decline.

Risks Related to the COVID-19 Pandemic

The COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease, may adversely affect our business, results of operations and financial condition.*

In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. The virus has spread globally. To date, our clinical trials have not been adversely affected by COVID-19, although certain practices we have adopted in our offices and facilities in an effort to promote social distancing have resulted in minor delays in the performance of administrative activities outside of the clinical programs. The spread of an infectious disease, including COVID-19, may result in the inability of our suppliers to deliver components or raw materials on a timely basis. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. While the extent of the impact of the current COVID-19 pandemic on our business and financial results depends on future developments that are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others, a continued and prolonged public health crisis such as the COVID-19 pandemic may adversely affect our business, results of operations and financial condition.

Travel restrictions related to the COVID-19 pandemic have delayed FDA and other regulatory authority inspections of our facilities required for approvals and there is no certainty with respect to the timing of such inspections.*

We are subject to inspection by the FDA and comparable foreign regulatory authorities to determine our compliance with applicable regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories. The FDA had advised us 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, which inspections have not yet been scheduled due to the FDA's travel restrictions resulting from the COVID-19 pandemic. As previously disclosed, in the recently issued CRL, the FDA noted that an inspection of our manufacturing facility in Israel is required before the FDA can approve the BLA. Due to travel restrictions as a result of the pandemic, the FDA was unable to conduct the required inspection during the review cycle. Also, with respect to the third-party facility in Europe at which fill and finish processes are performed for PRX-102, the FDA reviewed records under Section 704(a)(4) of the Federal Food, Drug and Cosmetic Act in lieu of a pre-licensing meeting. The FDA explained in the letter that it will continue to monitor the public health situation as well as travel restrictions and is actively working to define an approach for scheduling outstanding inspections. We cannot predict when such inspections will take place. Once such inspections are able to be conducted, if the facilities are not in substantial compliance with cGMP, there may be adverse consequences to the approval process. Delays in the approval process or our inability to obtain approval for any reason for any drug candidate may have a material adverse effect upon our business, results of operations and financial condition.

Risks Related to Clinical Trials and Regulatory Matters

We may not obtain the necessary U.S., EMA or other worldwide regulatory approvals to commercialize our drug candidates in a timely manner, if at all, which would have a material adverse effect on our business, results of operations and financial condition.*

We need FDA approval to commercialize our drug candidates in the United States, EMA approval to commercialize our drug candidates in the European Union and approvals from other foreign regulators to commercialize our drug candidates elsewhere. In order to obtain FDA approval of any of our drug candidates, we must submit to the FDA a BLA or an NDA demonstrating that the drug candidate is safe and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials. In the European Union, we must submit an MAA to the EMA. Satisfaction of the regulatory requirements of the FDA, EMA and other foreign regulatory authorities typically takes many years, depends upon the type, complexity and novelty of the drug candidate and requires substantial resources for research, development and testing.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings or other comparable authorities for such clinical trials. Further, even if favorable testing data is generated by the clinical trials of a drug candidate, the applicable regulatory authority may not accept or approve a marketing application we file for the drug candidate or may require us to conduct additional clinical testing or perform post-marketing studies which would cause us to incur additional costs.

Failure to obtain approval of the FDA, EMA or comparable foreign authorities of any of our drug candidates in a timely manner, if at all, will severely undermine our business, financial condition and results of operation by reducing our potential marketable products and our ability to generate corresponding product revenues.

In light of our receipt of a CRL from the FDA regarding our BLA for PRX-102, the U.S. regulatory requirements and timing for PRX-102 approval are uncertain; we are substantially dependent on receipt of regulatory approvals for PRX-102, our most advanced product candidate.*

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 CRL did not report any concerns relating to the potential safety or efficacy of PRX-102 in the submitted data package. However, in the CRL, the FDA noted that agalsidase beta (Fabrazyme), a therapy used to treat Fabry patients, was recently converted to full approval which must be addressed in the context of any potential resubmission seeking accelerated approval of PRX-102. We intend to work collaboratively with the agency to identify the most expeditious pathway to approval, including accelerated approval. We remain confident that we will be able to work with the FDA to resolve these issues and provide a new, alternative drug to Fabry patients. We, together with Chiesi, intend to request a Type-A meeting with the FDA. There can be no guarantee that the FDA will grant this request or, if granted, that this meeting will be held promptly. Furthermore, we cannot predict the outcome of any interactions with the FDA nor can we guarantee when, or if, we will be successful in receiving regulatory approval for PRX-102. The regulatory requirements and timing for approval are uncertain at this time. If we do not obtain approval for PRX-102 or are delayed in obtaining such approval, it would have a material and adverse effect on our operations and financial condition.

The FDA may request additional data or impose other conditions in connection with a resubmission or approval. We cannot assure you that the FDA will eventually approve PRX-102 on a resubmission.

In addition, we may incur significant additional expenditures in order to obtain or maintain FDA approval. Any approval of the BLA may also be subject to post-marketing commitments or requirements, and we may need to develop and/or improve certain antibody or additional assays as post-marketing requirements or commitments. Even if we comply with all the requests of regulatory authorities, the FDA and other authorities may ultimately reject the BLA or any other marketing application that we file for a product candidate in the future, if any, or we might not obtain regulatory clearance in a timely manner.

We also cannot assure you that the results of our ongoing *BALANCE* study will demonstrate that our product candidates are safe and effective for their intended uses.

The Fast Track designation for pegunigalsidase alfa for the treatment of Fabry disease may not lead to a faster development or regulatory review or approval process or increase the likelihood that pegunigalsidase alfa will receive regulatory approval for the treatment of Fabry disease.*

The FDA has granted Fast Track designation to pegunigalsidase alfa for the treatment of Fabry disease. As noted above, there can be no assurance that pegunigalsidase alfa will receive regulatory approval for the treatment of Fabry disease and following the receipt of the CRL timing for resubmission and the regulatory review process is uncertain. Despite the designation, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures. In addition, the FDA is entitled to withdraw the Fast Track designation of a drug candidate at any time. Any failure to realize the benefits of Fast Track designation may have a material adverse effect on our business, results of operations and financial condition.

We are subject to extensive governmental regulation including the requirements of the FDA and other comparable regulatory authorities before our drug candidates may be marketed.

Both before and after marketing approval of our drug candidates, if at all, we, our drug candidates, our suppliers, our contract manufacturers and our contract testing laboratories are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. Failure to comply with applicable requirements of the FDA or comparable foreign regulatory authorities could result in, among other things, any of the following actions:

- warning letters;
- fines and other monetary penalties;
- unanticipated expenditures;
- delays in the FDA's or other foreign regulatory authorities' approving, or the refusal of any regulatory authority to approve, any drug candidate;
- product recall or seizure;
- interruption of manufacturing or clinical trials;
- operating restrictions;
- injunctions; and
- criminal prosecutions.

In addition to the approval requirements, other numerous and pervasive regulatory requirements apply, both before and after approval, to us, our drug candidates, our suppliers, contract manufacturers, and contract testing laboratories. These include requirements related to:

- testing;
- manufacturing;
- quality control;
- labeling;
- advertising;
- promotion;
- distribution;

- export;
- reporting to the FDA certain adverse experiences associated with use of the drug candidate; and
- obtaining additional approvals for certain modifications to the drug candidate or its labeling or claims.

We also are subject to inspection by the FDA and comparable foreign regulatory authorities, to determine our compliance with regulatory requirements, as are our suppliers, contract manufacturers, and contract testing laboratories, and there can be no assurance that the FDA, or any other comparable foreign regulatory authority, will not identify compliance issues that may disrupt production or distribution, or require substantial resources to correct. We may be required to make modifications to our manufacturing operations in response to these inspections which may require significant resources and may have a material adverse effect upon our business, results of operations and financial condition.

The approval process for any drug candidate may also be delayed by changes in government regulation, future legislation or administrative action or changes in policy of the FDA and comparable foreign authorities that occur prior to or during their respective regulatory reviews of such drug candidate.

Delays in obtaining regulatory approvals with respect to any drug candidate will materially and adversely affect our prospects, business, results of operations and financial condition.

Delays in obtaining regulatory approvals with respect to any drug candidate may:

- delay commercialization of, and our ability to derive product revenues from, such drug candidate;
- delay any regulatory-related milestone payments payable under outstanding collaboration agreements;
- require us to perform costly procedures with respect to such drug candidate; or
- otherwise diminish any competitive advantages that we may have with respect to such drug candidate.

Delays in the approval process for any drug candidate will have a material adverse effect upon our prospects, business, results of operations and financial condition.

Clinical trials are very expensive, time-consuming and difficult to design and implement and may result in unforeseen costs, which may have a material adverse effect on our business, results of operations and financial condition.*

Human clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Preliminary and initial results from a clinical trial do not necessarily predict final results, and failure can occur at any stage of the trial. We may encounter problems that cause us to abandon or repeat preclinical studies or clinical trials. The clinical trial process is also time-consuming. Other than taliglucerase alfa, all of our other drug candidates, including pegunigalsidase alfa, are in the clinical, preclinical or research stages. Our clinical program for pegunigalsidase alfa is in the middle of phase III, but generally, clinical programs take at least several years to complete.

Given the receipt of the CRL, we may be required, in connection with a resubmission to the FDA, to conduct additional clinical trials or undertake additional studies, which may require additional time and resources.

Failure or delay in the commencement or completion of our clinical trials may be caused by several factors, including:

- slower than expected rates of patient recruitment, particularly with respect to trials of rare diseases such as Fabry disease;
- determination of dosing issues;
- unforeseen safety issues;
- lack of effectiveness during clinical trials;

- disagreement by applicable regulatory bodies over our trial protocols, the interpretation of data from preclinical studies or clinical trials or conduct and control of clinical trials;
- determination that the patient population participating in a clinical trial may not be sufficiently broad or representative to assess efficacy and safety for our target population;
- inability to monitor patients adequately during or after treatment;
- inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and
- lack of sufficient funding to finance the clinical trials.

Any failure or delay in commencement or completion of any clinical trials of pegunigalsidase alfa or our other product candidates will have a material adverse effect on our business, results of operations and financial condition. In addition, we or the FDA or other regulatory authorities may suspend any clinical trial at any time if it appears that we are exposing participants in the trial to unacceptable safety or health risks or if the FDA or such other regulatory authorities, as applicable, find deficiencies in our IND submissions or the conduct of the trial. Any suspension of a clinical trial may have a material adverse effect on our business, results of operations and financial condition.

If the results of our clinical trials do not support our claims relating to a drug candidate, or if serious side effects are identified, the completion of development of such drug candidate may be significantly delayed or we may be forced to abandon development altogether, which will significantly impair our ability to generate product revenues.*

The results of our clinical trials with respect to any drug candidate might not support our claims of safety or efficacy, the results of our clinical trials may fail to conclusively show superiority over other commercially available treatments for the same or similar indications, the effects of our drug candidates may not be the desired effects or may include undesirable side effects or the drug candidates may have other unexpected characteristics. Data obtained from tests are susceptible to varying interpretations which may delay, limit or prevent regulatory approval. The clinical trial process may fail to demonstrate that our drug candidates are safe for humans and effective for indicated uses. In addition, our clinical trials, may involve specific and small patient populations. Results of early clinical trials conducted on a small patient population may not be indicative of future results. Adverse or inconclusive results may cause us to abandon a drug candidate and may delay development of other drug candidates. Any delay in, or termination of, our clinical trials will delay the filing of NDAs and BLAs with the FDA, or other filings with other foreign regulatory authorities, and, ultimately, significantly impair our ability to commercialize our drug candidates and generate product revenues which would have a material adverse effect on our business, results of operations and financial condition.

Interim, topline or preliminary data from clinical trials that we announce or publish may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.*

We may publicly disclose interim, topline or preliminary data from our clinical trials, which is based on a preliminary analysis of then-available data. The results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also may make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, any interim, topline or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different than the preliminary data we previously publish. As a result, any topline data should be viewed with caution until final data are available. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more data becomes available. Further, regulatory agencies may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or ascribe different weight to the data, which may impact the value of the clinical trial and may affect the particular clinical program and the approvability or commercialization of the particular product candidate and our business in general. If regulatory authorities disagree with the conclusions we reach, we may not be able to obtain approval for and commercialize our product candidates, which will have a material adverse effect on our business, results of operations and financial condition.

We may find it difficult to enroll patients in our clinical trials, or patients may discontinue their participation in our clinical trials, which could cause significant delays in the completion of such trials or may negatively impact the results of these studies and extend the timeline for completion of our development programs or cause us to abandon one or more clinical trials.

Some of the diseases or disorders that our drug candidates are intended to treat are relatively rare and we expect only a subset of the patients with these diseases to be eligible for our clinical trials. Our clinical trials generally mandate that a patient cannot be involved in another clinical trial for the same indication. Therefore, subjects that participate in ongoing clinical trials for products that are competitive with our drug candidates are not available for our clinical trials. An inability to enroll a sufficient number of patients for any of our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, patients that enroll in our clinical trials may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent, experiencing adverse clinical events, which may or may not be judged related to our drug candidates under evaluation, or due to planned or actual pregnancies. The discontinuation of patients in any one of our studies may delay the completion of the study or cause the results from the study not to be positive or to not support a filing for regulatory approval of the applicable drug candidate. Any failure to enroll a sufficient number of patients in our clinical trials in a timely manner, if at all, may have a material adverse effect on our business, results of operations and financial condition.

Because our clinical trials depend upon third-party researchers, the results of our clinical trials and such research activities are subject to delays and other risks which are, to a certain extent, beyond our control, which could impair our clinical development programs and our competitive position.

We depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials. These collaborators are not our employees, and we cannot control the amount or timing of resources that they devote to our clinical development programs. The investigators may not assign as great a priority to our clinical development programs or pursue them as diligently as we would if we were undertaking such programs directly. If outside collaborators fail to devote sufficient time and resources to our clinical development programs, or if their performance is substandard, the approval of anticipated NDAs, BLAs and other marketing applications, and our introduction of new drugs, if any, may be delayed which could impair our clinical development programs and would have a material adverse effect on our business, results of operations and financial condition. Our collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators also assist our competitors, our competitive position could be harmed.

We have only limited experience in regulatory affairs, and some of our drug candidates may be based on new technologies. These factors may affect our ability or the time we require to obtain necessary regulatory approvals.

We have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals for medical devices and drug candidates. Moreover, some of the drug candidates that are likely to result from our development programs may be based on new technologies that have not been extensively tested in humans. The regulatory requirements governing these types of drug candidates may be less well defined or more rigorous than for conventional products. As a result, we may experience a longer regulatory process in connection with obtaining regulatory approvals of any products that we develop, which may have a material adverse effect on our business, results of operations and financial condition.

Orphan drug designation may not ensure that we will enjoy market exclusivity in any jurisdiction. If any of our other competitors are able to obtain orphan drug exclusivity for any products that are competitive with our products, we may be precluded from selling or obtaining approval of our competing products by the applicable regulatory authorities for a significant period of time.

In the United States, the European Union and other countries, a drug may be designated as having orphan drug status, subject to certain conditions. There can be no assurance that a drug candidate that receives orphan drug designation will receive orphan drug marketing exclusivity and more than one drug can have orphan designation for the same indication. In addition, the orphan drug designation granted to pegunigalsidase alfa by the EMA does not affect Fabry disease treatments that preexist the approval of pegunigalsidase alfa, if at all.

Foreign regulations regarding orphan drugs are similar to those in the United States but there are several differences. For example, the exclusivity period in the European Union is generally 10 years. From time to time, we may apply to the FDA or any comparable foreign regulatory authority for orphan drug designation for any one or more of our drug candidates. Other than pegunigalsidase alfa which was granted orphan drug designation by the EMA, none of our drug candidates have been designated as an orphan drug and there is no guarantee that the FDA or any other regulatory authority will grant such designation in the future. In addition, neither

orphan drug designation nor orphan drug exclusivity prevents competitors from developing or marketing different drugs for the relevant indication. Even if we obtain orphan drug exclusivity for one or more indications for one of our drug candidates, we may not be able to maintain the exclusivity. For example, if a competitive product that is the same drug or biologic as one of our drug candidates is shown to be clinically superior to the drug candidate, any orphan drug exclusivity granted to the drug candidate will not block the approval of the competitive product.

If any drug receives orphan drug exclusivity in any jurisdiction for the same indication of any of our drug candidates, we may be prevented from attaining a similar designation with respect to our drug candidate or from marketing the drug candidate in the jurisdiction during the applicable exclusivity period, which will have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Our Business

We have a limited operating history which may limit the ability of investors to make an informed investment decision.

Taliglucerase alfa is our only commercial product. The successful commercialization of our other drug candidates will require us to perform a variety of functions, including:

- continuing to perform preclinical development and clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing and staffing our company, acquiring, developing and securing our proprietary technology and undertaking, through third parties, preclinical trials and clinical trials of our principal drug candidates. These operations provide a limited basis for investors to assess our ability to commercialize our drug candidates and whether to invest in our company.

We currently depend heavily on the success of pegunigalsidase alfa. Any failure to commercialize pegunigalsidase alfa, or the experience of significant delays in doing so, will have a material adverse effect on our business, results of operations and financial condition.*

We are investing a significant portion of our efforts and financial resources in the development of pegunigalsidase alfa and our ability to generate significant product revenues in the future, will depend heavily on the successful development and commercialization of pegunigalsidase alfa. The successful commercialization of pegunigalsidase alfa will depend on several factors, including the following:

- successful completion of our ongoing studies of pegunigalsidase alfa;
- Chiesi’s efforts under the Chiesi Agreements;
- identifying a path for resubmission to, and ultimately obtaining marketing approvals from, the FDA;
- obtaining marketing approvals from the EMA and other foreign regulatory authorities;
- maintaining the cGMP compliance of our manufacturing facility or establishing manufacturing arrangements with third parties;
- the successful inspection of our facilities by the FDA and other foreign regulatory authorities;
- raising additional capital, if necessary, in order to fund any additional clinical trials required in connection with the resubmission to the FDA or to continue to fund our operations in light of an extended regulatory pathway during which time period we cannot expect to receive additional milestone payments under the Chiesi Agreements;

- Chiesi's development of successful sales and marketing organizations for pegunigalsidase alfa;
- the availability of reimbursement to patients from healthcare payors for pegunigalsidase alfa, if approved;
- a continued acceptable safety and efficacy profile of pegunigalsidase alfa following approval; and
- other risks described in these Risk Factors.

Any failure to commercialize pegunigalsidase alfa or the experience of significant delays in doing so will have a material adverse effect on our business, results of operations and financial condition.

Any failure by us to supply drug substance to Pfizer may have a material adverse effect on our business, results of operations and financial condition.

Under the Amended Pfizer Agreement, we have agreed, for the first 10-year period after the execution of the agreement, 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. As part of that obligation, we agreed to substantial financial penalties in case we fail to comply with the supply commitments, or are delayed in doing so. The amounts of the penalties depend on when any such failure occurs and for how long it persists, if at all, and other considerations. Any failure to comply with the supply commitments under the Amended Pfizer Agreement may have a material adverse effect on our business, results of operations and financial condition.

Our strategy, in certain cases, is to enter into collaboration agreements with third parties to leverage our ProCellEx system to develop product candidates. Failure to enter into such agreements, or non-compliance by us or our collaborators with such agreements, may have a material adverse effect on our business, results of operations and financial condition.

Our strategy, in certain cases, is to enter into arrangements with pharmaceutical companies to leverage our ProCellEx system to develop additional product candidates. Under these arrangements, we may grant to our partners rights to license and commercialize pharmaceutical products developed under the applicable agreements, as we have done with Elelyso and pegunigalsidase alfa, and more recently, with alidornase alfa. Our partners may control key decisions relating to the development of the products and we may depend on our partners' expertise and dedication of sufficient resources to develop and commercialize our product candidates. The rights of our partners limit our flexibility in considering alternatives for the commercialization of our product candidates. If we or any of our current or future partners breach or terminate the agreements that make up such arrangements, our partners otherwise fail to conduct their obligations under such arrangements in a timely manner, there is a dispute about their obligations or if either party terminates the applicable agreement or elects not to continue the arrangement, we may not enjoy the benefits of the agreements or receive a sufficient amount of royalty or milestone payments from them, if any, which may have a material adverse effect on our business, results of operations and financial condition.

If we are unable to develop and commercialize our product candidates, our business will be adversely affected.

A key element of our strategy is to develop and commercialize a portfolio of new products in addition to taliglucerase alfa. We seek to do so through our internal research programs and strategic collaborations for the development of new products. Research programs to identify new product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following:

- a product candidate is not capable of being produced in commercial quantities at an acceptable cost, or at all;
- a product candidate may not be accepted by patients, the medical community or third-party payors;
- competitors may develop alternatives that render our product candidates obsolete;
- the research methodology used may not be successful in identifying potential product candidates; or
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory approval.

Any failure to develop or commercialize any of our other product candidates may have a material adverse effect on our business, results of operations and financial condition.

The manufacture of our products is an exacting and complex process, and any manufacturing problems encountered by us or certain of our suppliers may have a material adverse effect on our business, results of operations and financial condition.

The FDA and foreign regulators require manufacturers to register manufacturing facilities. The FDA and foreign regulators also inspect these facilities to confirm compliance with cGMP or similar requirements that the FDA or foreign regulators establish. We or certain of our materials suppliers may face manufacturing or quality control problems causing product production and shipment delays or a situation where we or the supplier may not be able to maintain compliance with the FDA's cGMP requirements, or those of foreign regulators, necessary to continue manufacturing. To date, our current facility has passed audits by the FDA and a number of other regulatory authorities but remains subject to audit by other foreign regulatory authorities. There can be no assurance that we will be able to comply with FDA or foreign regulatory manufacturing requirements for our current facility or any facility we may establish in the future, and the failure to so comply will have a material adverse effect on our business, results of operations and financial condition.

We rely on third parties for final processing of taliglucerase alfa, pegunigalsidase alfa and our other product candidates, which exposes us to a number of risks that may delay development, regulatory approval and commercialization of taliglucerase alfa and our other product candidates or result in higher product costs.

We have no experience in the final filling and freeze drying steps of the drug manufacturing process. We rely on third parties in the United States and Europe to perform fill and finish activities for taliglucerase alfa and pegunigalsidase alfa, and have engaged other parties for our other product candidates. We may be unable to identify manufacturers and/or replacement manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA and other regulatory authorities, as applicable, must approve any manufacturer and/or replacement manufacturer, including us, and we or any such third party manufacturer might be unable to formulate and manufacture our drug products in the volume and of the quality required to meet our clinical and commercial needs. If we engage any contract manufacturers, such manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical or commercial needs. In addition, contract manufacturers are subject to the rules and regulations of the FDA and comparable foreign regulatory authorities and face the risk that any of those authorities may find that they are not in compliance with applicable regulations. Each of these risks, if realized, could delay our clinical trials, the approval, if any, of our potential drug candidates by the FDA and other regulatory authorities, or the commercialization of our drug candidates or could result in higher product costs or otherwise deprive us of potential product revenues.

Developments by competitors may render our products or technologies obsolete or non-competitive which would have a material adverse effect on our business, results of operations and financial condition.

We compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Our drug candidates will have to compete with existing therapies and therapies under development by our competitors. Our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug products. Other companies have drug candidates in various stages of preclinical or clinical development to treat diseases for which we are also seeking to develop drug products. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. See Business – Competition.

Most of our competitors, either alone or together with their collaborative partners, operate larger research and development programs, staff and facilities and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking preclinical testing and human clinical trials;
- obtaining marketing approvals from the FDA and other regulatory authorities;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

These organizations also compete with us to attract qualified personnel, acquisitions and joint ventures candidates and for other collaborations. Activities of our competitors may impose unanticipated costs on our business or adversely affect the market for our drug products which would have a material adverse effect on our business, results of operations and financial condition.

If we in-license drug candidates, we may delay or otherwise adversely affect the development of our existing drug candidates, which may negatively impact our business, results of operations and financial condition.

In addition to our own internally developed drug candidates, we proactively seek opportunities to in-license and advance other drug candidates that are strategic and have value-creating potential to take advantage of our development know-how and technology. In-licensing additional drug candidates may significantly increase our capital requirements, and place a strain on the time of our existing personnel, which may delay or otherwise adversely affect the development of our existing drug candidates or cause us to re-prioritize our drug pipeline if we do not have the necessary capital resources to develop all of our drug candidates, which may have a material adverse impact on our business, results of operations and financial condition.

If we are unable to manage future growth successfully there could be a material adverse impact on our business, results of operations and financial condition.

To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability on the part of our management to manage growth could delay the execution of our business plans or disrupt our operations. If we are unable to manage our growth effectively, we may not use our resources in an efficient manner, which may delay the development of our drug candidates and materially and adversely impact our business, results of operations and financial condition.

If we acquire companies, products or technologies, we may face integration risks and costs associated with those acquisitions that could negatively impact our business, results of operations and financial condition.

If we are presented with appropriate opportunities, we may acquire or make investments in complementary companies, products or technologies. If we acquire companies or technologies, we will face risks, uncertainties and disruptions associated with the integration process, including difficulties in the integration of the operations of an acquired company, integration of acquired technology with our products, diversion of our management's attention from other business concerns, the potential loss of key employees or customers of the acquired business and impairment charges if future acquisitions are not as successful as we originally anticipate. In addition, our operating results may suffer because of acquisition-related costs or amortization expenses or charges relating to acquired intangible assets. Any failure to successfully integrate other companies, products or technologies that we may acquire may have a material adverse effect on our business and results of operations. Furthermore, we may have to incur debt or issue equity securities to pay for any additional future acquisitions or investments, the issuance of which could be dilutive to our existing stockholders.

We depend upon key employees and consultants in a competitive market for skilled personnel. If we are unable to attract and retain key personnel, it could adversely affect our ability to develop and market our products.

We are highly dependent upon the principal members of our management team, especially our President and Chief Executive Officer, Dror Bashan, as well as the Chairman of our Board of Directors, Zeev Bronfeld, our other directors, consultants and collaborating scientists. Many of these people have been involved with us for many years and have played integral roles in our progress, and we believe that they will continue to provide value to us. A loss of any of these personnel may have a material adverse effect on aspects of our business, clinical development and regulatory programs. We have employment agreements with Mr. Bashan and our other executive officers that may be terminated by us or the applicable officer at any time with varying notice periods of 60 to 180 days. The loss of any of these persons' services may adversely affect our ability to develop and market our products and obtain necessary regulatory approvals. Further, we do not maintain key-man life insurance.

We also depend in part on the continued service of our key scientific personnel and our ability to identify, hire and retain additional personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to suit from their former employers. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel.

Our collaborations with outside scientists and consultants may be subject to restriction and change.

We work with medical experts, biologists, chemists and other scientists at academic and other institutions, and consultants who assist us in our research, development, regulatory and commercial efforts, including the members of our scientific advisory board. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice regarding our programs. These scientists and consultants are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product or compound that is more scientifically interesting to his or her professional or academic interests, his or her availability to remain involved in our clinical trials could be restricted or eliminated, which may have a material adverse effect on our business, results of operations and financial condition.

Under current U.S. and Israeli law, we may not be able to enforce employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We have entered into non-competition agreements with substantially all of our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under current U.S. and Israeli law, we may be unable to enforce these agreements against most of our employees and it may be difficult for us to restrict our competitors from gaining the expertise our former employees gained while working for us. If we cannot enforce our employees' non-compete agreements, we may be unable to prevent our competitors from benefiting from the expertise of our former employees, which may have a material adverse effect on our business, results of operations and financial condition.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. While our assessment of our internal control over financial reporting resulted in our conclusion that as of December 31, 2020, our internal control over financial reporting was effective, we cannot predict the outcome of our testing or any subsequent testing by our auditor in future periods. Any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information and affect our reputation, which could have an adverse effect on the trading price of our common stock.

Our management is required to assess the effectiveness of our internal controls and procedures and disclose changes in these controls on an annual basis. However, for as long as we are a non accelerated filer, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

Our internal computer systems, or those used by our third-party contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our present and future contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Although to our knowledge we have not experienced any material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. We have

a cybersecurity insurance policy to protect us from such risks. However, to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability despite our insurance policy, and the further development and commercialization of our product candidates could be delayed.

We could be subject to securities class action litigation.*

Securities class action litigation is often brought against a company following a period of volatility or decline in the market price of its securities. As with pharmaceutical companies generally, our company has experienced significant stock price volatility in recent years. If we become subject to such litigation, we will face substantial costs and a diversion of management's attention and resources, which could have a material adverse affect on our business, results of operation and financial condition.

If product liability claims are brought against us, it may result in reduced demand for our products and product candidates or damages that exceed our insurance coverage.

The clinical testing, marketing and use of our products and product candidates exposes us to product liability claims if the use or misuse of those products or product candidates cause injury or disease, or results in adverse effects. Use of our products or product candidates, whether in clinical trials or post approval, could result in product liability claims. We presently carry clinical trial liability insurance with coverages of up to $10.0 million per occurrence and $10.0 million in the aggregate, an amount we consider reasonable and customary. However, this insurance coverage includes various deductibles, limitations and exclusions from coverage, and in any event might not fully cover any potential claims. We may need to obtain additional clinical trial liability coverage prior to initiating additional clinical trials. We expect to obtain product liability insurance coverage before commercialization of our product candidates; however, such insurance is expensive and insurance companies may not issue this type of insurance when we need it. We may not be able to obtain adequate insurance in the future at an acceptable cost. Any product liability claim, even one that was not in excess of our insurance coverage or one that is meritless and/or unsuccessful, may adversely affect our cash available for other purposes, such as research and development, which may have a material adverse effect on our business, results of operations and financial condition. Product liability claims, even if without merit, may result in reduced demand for our products, if approved, or result in adverse market reactions, which would have a material adverse effect on our business, results of operations and financial condition.

Reforms in the healthcare industry and the uncertainty associated with pharmaceutical pricing, reimbursement and related matters could adversely affect the marketing, pricing and demand for our products, if approved.

Increasing healthcare expenditures have been the subject of considerable public attention in the United States. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would result in changes in the U.S. healthcare system are continuously introduced or proposed in the U.S. Congress and in some state legislatures within the United States, including reductions in the pricing of prescription products and changes in the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products. Legislation and regulations that reduce reimbursement for our product candidates could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our product candidates, if approved. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our products, if approved. In addition, we believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales, upon approval, if at all.

Governments outside the United States tend to impose strict price controls and reimbursement approval policies, which may adversely affect our prospects for generating revenue.

In some countries, particularly European Union member states, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time (six to 12 months or longer) after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries with respect to any product candidate that achieves regulatory approval, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. Any unavailability or limitation on the reimbursement of our products upon approval, if at all, or the determination of unsatisfactory reimbursement prices, may have a material adverse effect on our business, results of operations and financial condition. Further, if we achieve regulatory approval of any product, we must successfully negotiate product pricing for such product in individual countries. As a result, the pricing of our product candidates, if approved, in different countries may vary widely, thus creating the potential for third-party trade in our products in an attempt to

exploit price differences between countries. This third-party trade of our products could undermine our sales in markets with higher prices which could have a material adverse effect on our business, results of operations and financial condition.

Our ability to utilize net operating loss carryforwards may be limited.

Our net operating losses, or NOLs, as of December 31, 2020, are equal to approximately $231.4 million, of which approximately $30.9 million may be restricted under Section 382 of the Internal Revenue Code, or the IRC. IRC Section 382 applies whenever a corporation with NOLs experiences an ownership change. As a result of IRC Section 382, the taxable income for any post-change year that may be offset by a pre-change NOL may not exceed the fair market value of the pre-change entity multiplied by the IRC long-term tax exempt rate. Significant judgment is required in determining any valuation allowance recorded against deferred tax assets. In assessing the need for a valuation allowance, we considered all available evidence, including past operating results, the most recent projections for taxable income and prudent and feasible tax planning strategies. We reassess our valuation allowance periodically and if future evidence allows for a partial or full release of the valuation allowance, a tax benefit will be recorded accordingly. Any ownership change (including as a result of conversion of our outstanding convertible notes into shares of our common stock), or any other limitation on our utilization of NOLs, could have a material adverse effect on our business, results of operations and financial condition.

Our corporate structure may create U.S. federal income tax inefficiencies

Protalix Ltd. is our wholly-owned subsidiary and thus a controlled foreign corporation of our company for U.S. federal income tax purposes. This organizational structure may create inefficiencies, as certain types of income and investments of Protalix Ltd. that otherwise would not be currently taxable under general U.S. federal income tax principles may become taxable. These inefficiencies may require us to use more of our NOLs than we otherwise might and may result in a tax liability without a corresponding distribution from our subsidiary which could have a material adverse effect on our business, results of operations and financial condition.

We are a holding company with no operations of our own.

We are a holding company with no operations of our own. Accordingly, our ability to conduct our operations, service any debt that we may incur in the future and pay dividends, if any, is dependent upon the earnings from the business conducted by Protalix Ltd. The distribution of those earnings or advances or other distributions of funds by our subsidiary to us, as well as our receipt of such funds, are contingent upon the earnings of Protalix Ltd. and are subject to various business considerations and U.S. and Israeli law. If Protalix Ltd. is unable to make sufficient distributions or advances to us, or if there are limitations on our ability to receive such distributions or advances, we may not have the cash resources necessary to conduct our corporate operations or service our debt which would have a material adverse effect on our business, results of operations and financial condition.

Risks Related to our Financial Condition and Capital Requirements

Servicing our debt and settling conversion requests may require a significant amount of cash, and we may not have sufficient cash flow from our business to pay our debt. Furthermore, restrictive covenants governing our indebtedness may restrict our ability to raise additional capital.*

We currently have outstanding $57.9 million aggregate principal amount of our 2021 Notes which are secured with a perfected lien on all of our assets. Under the terms of the indenture governing the 2021 Notes, we are required to maintain a minimum cash balance of at least $7.5 million. Our ability to make payments with respect to the 2021 Notes and to satisfy any other debt obligations depends on our future operating performance and our ability to generate significant cash flow in the future, which will be affected by prevailing economic conditions and financial, business, competitive, legislative and regulatory factors as well as other factors affecting our company and industry, many of which are beyond our control. If, when required, we are unable to comply with the terms of the 2021 Notes, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. In addition, certain terms of the 2021 regarding the security interest or future indebtedness may restrict us from adopting any of these alternatives. We may be unable to obtain amendments and waivers of such restrictions. If there is a default of such notes, the note holders could, among other things, elect to declare all amounts owed immediately due and payable, which could cause all or a large portion of our available cash flow to be used to pay such amounts and thereby reduce the amount of cash available to pursue our business plans or force us into bankruptcy or liquidation, or, with respect to our indebtedness that is secured, result in the foreclosure on the assets that secure the debt, which would force us to relinquish rights to assets that we may believe are critical to our business. Any default on our debt will have a material adverse effect on our business, results of operations and financial condition.

Our significant level of indebtedness could adversely affect our business, results of operations and financial condition and prevent us from fulfilling our obligations under our convertible notes and our other indebtedness.

Our 2021 Notes represent a significant amount of indebtedness with substantial debt service requirements. We may also incur additional indebtedness to meet future financing needs. Our substantial indebtedness could have material adverse effects on our business, results of operations and financial condition. For example, it could:

- make it more difficult for us to satisfy our financial obligations, including with respect to the convertible notes;
- result in an event of default under our outstanding convertible notes if we fail to comply with the financial and other restrictive covenants contained in agreements governing any future indebtedness, which event of default could result in all of our debt becoming immediately due and payable;
- increase our vulnerability to general adverse economic, industry and competitive conditions;
- reduce the availability of our cash flow to fund working capital, capital expenditures, acquisitions and other general corporate purposes because we will be required to dedicate a substantial portion of our cash flow from operations to the payment of principal and interest on our indebtedness;
- limit our flexibility in planning for, or reacting to, and increasing our vulnerability to changes in our business, the industry in which we operate and the general economy;
- prevent us from raising funds necessary to purchase convertible notes surrendered to us by holders upon a fundamental change (as described in the indenture governing the notes), which failure would result in an event of default with respect to the convertible notes;
- place us at a competitive disadvantage compared to our competitors that have less indebtedness or are less highly leveraged and that, therefore, may be able to take advantage of opportunities that our debt levels or leverage prevent us from exploiting; and
- limit our ability to obtain additional financing.

Each of these factors may have a material and adverse effect on our business, results of operations and financial condition and our ability to meet our payment obligations under the convertible notes and our other indebtedness.

Any conversion of our outstanding convertible notes into common stock will dilute the ownership interest of our existing stockholders, including holders who had previously converted their notes.

The conversion of some or all of our convertible notes into shares of our common stock will dilute the ownership interests of our existing stockholders. Any sales in the public market of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. In addition, the existence of our outstanding convertible notes may encourage short selling by market participants because the conversion of convertible notes could depress the market price of our common stock.

The fundamental change purchase feature of our outstanding convertible notes may delay or prevent an otherwise beneficial attempt to take over our company.

The terms of our outstanding convertible notes require us to offer to purchase the notes for cash in the event of a fundamental change. A non-stock takeover of our company may trigger the requirement that we purchase the notes. This feature may have the effect of delaying or preventing a takeover of our company that would otherwise be beneficial to our stockholders.

We may fail to meet the continued market capitalization-based listing requirement or other continued listing requirements of The NYSE American.*

The stock market in general, and the market for pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of the listed companies. The trading price of our common stock has been volatile and has been subject to wide price fluctuations in response to various factors, many of which are beyond our control. The volatility of our stock price has from time to time in recent periods affected our market capitalization.

Adverse fluctuations in the price per share of our common stock or our market capitalization may result in our failure to meet the continued listing requirements of The NYSE American, which would require us to take steps to gain compliance with alternate listing standards or take remedial steps to bring us into compliance. A failure to maintain or regain compliance with applicable listing standards could adversely affect the liquidity of our common stock and could result in an event of default under the indenture governing our 2021 Notes, which would have a material adverse effect on our business, results of operations and financial condition.

We currently have no significant product revenues and need to raise additional capital to operate our business, which may not be available on favorable terms, or at all, and which will have a dilutive effect on our stockholders.*

To date, we have not generated significant revenues from product sales and only minimal revenues from research and development services and other fees, other than the milestone and other payments we have received in connection with our agreements with Pfizer and Chiesi. For the years ended December 31, 2020, 2019 and 2018, we had net losses from continuing operations of $6.5 million, $18.3 million and $26.5 million, respectively, and for the quarter ended March 31, 2021, we had net losses from continuing operations of $5.5 million, primarily as a result of expenses incurred through a combination of research and development activities and expenses supporting those activities, which includes share-based compensation expense. Drug development and commercialization is very capital intensive. We fund all of our operations and capital expenditures from the revenues we generate from licensing fees and grants, the net proceeds of equity and debt offerings and other sources. In addition, changes may occur that could consume our existing capital at a faster rate than projected, including, among others, the cost and timing of regulatory approvals, changes in the progress of our research and development efforts and the costs of protecting our intellectual property rights.

We will need to finance our future cash needs through corporate collaboration, licensing or similar arrangements, public or private equity offerings or debt financings. To the extent that the regulatory pathway for our lead product candidate, PRX-102, is delayed and we must conduct additional clinical trials in light of the FDA CRL in connection with a resubmission or otherwise, we may be required to seek to raise additional capital. If we are unable to secure additional financing in the future on acceptable terms, or at all, we may be unable to commence or complete planned preclinical and clinical trials or obtain approval of our drug candidates from the FDA and other regulatory authorities. In addition, we may be forced to reduce or discontinue product development or product licensing, reduce or forego sales and marketing efforts and other commercialization activities or forego attractive business opportunities in order to improve our liquidity and to enable us to continue operations which would have a material adverse effect on our business and results of operations. Furthermore, any additional source of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and delays in achieving profitability, if at all, will have a material adverse effect on our business and results of operations and could negatively impact the value of our common stock.

We may incur losses for the foreseeable future. We expect to continue to incur significant operating expenditures, and we anticipate that our expenses will increase in the foreseeable future as we:

- continue to undertake preclinical development and clinical trials for our current and new drug candidates;
- seek regulatory approvals for our drug candidates; and
- seek to in-license additional technologies.

We also may continue to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the foreseeable future, if at all. Delays in achieving profitability, or subsequent failures to maintain profitability, will have a material adverse effect on our business and results of operations and could negatively impact the value of our common stock.

Risks Related to the Commercialization of Drug Products

There has been continued non-compliance with the terms and conditions of the Brazil Agreement.

We do not control and may not be able to effectively influence Fiocruz’s ability to distribute BioManguinhos alfataliglicerase in Brazil. Any failure by Fiocruz to comply with the purchase requirements of the Brazil Agreement, or any other material breach by Fiocruz of the agreement, may have a material adverse effect on our business, results of operations and financial condition.

We face the risk of lower than anticipated purchases of BioManguinhos alfataliglicerase by the Brazilian MoH. In addition, we may fail to supply the intended amounts on time, if at all. We also cannot accurately predict the amount of revenues we will generate under the Brazil Agreement in future periods, if any. Any failure by the Brazilian MoH to purchase BioManguinhos alfataliglicerase, by us to supply BioManguinhos alfataliglicerase for purchase or by Fiocruz to distribute BioManguinhos alfataliglicerase in Brazil, or the experience of significant delays in any of the foregoing, may have a material adverse effect on our business, results of operations and financial condition.

We have limited experience in selling, marketing or distributing products and limited internal capability to do so.

We currently have very limited sales, marketing or distribution capabilities and no experience in building a sales force and distribution capabilities. Under our arrangements with Pfizer, Chiesi and SarcoMed, we have out-licensed the marketing rights to Elelyso, pegunigalsidase alfa and alidornase alfa via inhalation, except that we retained the marketing rights to BioManguinhos alfataliglicerase in Brazil. We have not licensed the marketing or commercialization rights to any of our other product candidates to any party. The commercialization of a drug product requires that we commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

- the inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to an adequate numbers of physicians or to pursuance them to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

We may not be successful in recruiting or retaining the sales and marketing personnel necessary to sell BioManguinhos alfataliglicerase or any of our products upon approval, if at all, which would have a material adverse effect on our business, results of operations and financial condition.

We may enter into distribution arrangements and marketing alliances for certain products and any failure to successfully identify and implement these arrangements on favorable terms, if at all, may impair our ability to commercialize our product candidates.

We may need to establish a sales force to market one or more of our product candidates, if approved. We do not anticipate having the resources in the foreseeable future to develop global sales and marketing capabilities for all of the products we are developing. We may elect to pursue arrangements regarding the sales and marketing and distribution of one or more of our product candidates, and our future revenues may depend, in part, on our ability to enter into and maintain arrangements with other companies having sales, marketing and distribution capabilities and the ability of such companies to successfully market and sell any such products. Any failure to enter into such arrangements and marketing alliances on favorable terms, if at all, could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Any use of distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including the following:

- we may be required to relinquish important rights to our products or product candidates;
- we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;
- our distributors or collaborators may experience financial difficulties;
- our distributors or collaborators may not devote sufficient time to the marketing and sales of our products; and
- business combinations or significant changes in a collaborator’s business strategy may adversely affect a collaborator’s willingness or ability to complete its obligations under any arrangement.

We may need to enter into additional co-promotion arrangements with third parties where our own sales force is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements we enter into may not be favorable to us.

If physicians, patients, third party payors and others in the medical community do not accept and use taliglucerase alfa, or any of our other product candidates, if approved, our ability to generate revenue from product sales will be materially impaired.

Physicians and patients, and other healthcare providers, may not accept and use any of our products or any product candidates, if approved for marketing. Future acceptance and use of any of our products or any product candidates, if approved, will depend upon a number of factors including:

- perceptions by physicians, patients, third party payors and others in the medical community about the safety and effectiveness of taliglucerase alfa or our other drug candidates;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the prevalence and severity of any side effects, including any limitations or warnings contained in our products' approved labeling;
- pharmacological benefits of taliglucerase alfa or our other drug candidates relative to competing products and products under development;
- the efficacy and potential advantages relative to competing products and products under development;
- relative convenience and ease of administration;
- effectiveness of education, marketing and distribution efforts by us and our licensees and distributors, if any;
- publicity concerning taliglucerase alfa or our other drug candidates or competing products and treatments;
- coverage and reimbursement of our products by third party payors; and
- the price for our products and competing products.

A lack of market acceptance of BioManguinhos alfataliglicerase in Brazil, or globally for any of our other products candidates, if approved, would have a material adverse effect on our business, results of operations and financial condition.

If the market opportunities for other product candidates, and for BioManguinhos alfataliglicerase in Brazil, are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

To date, our development efforts have focused mainly on relatively rare disorders with small patient populations, in particular Gaucher disease and Fabry disease. Currently, most reported estimates of the prevalence of these diseases are based on studies of small subsets of the population of specific geographic areas, which are then extrapolated to estimate the prevalence of the diseases in the broader world population. As new studies are performed, the estimated prevalence of these diseases may change. There can be no assurance that the prevalence of Gaucher disease or Fabry disease in the study populations, particularly in these newer studies, accurately reflect the prevalence of these diseases in the broader world population. If the market opportunities for our current product candidates are smaller than we believe they are, our revenues may be adversely affected and our business may suffer.

Coverage and reimbursement may not be available for one or more of our product candidates, if approved, in all territories, which could diminish our sales or affect our ability to sell any such products profitably.

Market acceptance and sales of any one or more of our product candidates, if approved, will depend on coverage and reimbursement policies in the countries in which they are approved for sale. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. Obtaining reimbursement approval for an approved product from governments and other third party payors is a time consuming and costly process that requires our collaborators or us, as the case may be, to provide supporting scientific, clinical and cost-effectiveness data for the use of our products, if and when approved, to every payor. We may not be able to provide data sufficient to gain acceptance

with respect to coverage and reimbursement or we might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of approved products, if any, to such payors' satisfaction. Such studies might require our collaborators or us to commit a significant amount of management time and financial and other resources. Even if a payor determines that an approved product is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other regulatory authorities. In addition, full reimbursement may not be available for high priced products. Moreover, eligibility for coverage does not imply that any approved product will be reimbursed in all cases or at a rate that allows us to make a profit or even cover our costs. Limited reimbursement amounts may reduce the demand for, or the price of, our product candidates. If coverage and reimbursement are not available or are available only to limited levels, the sales of our products, if approved, may be diminished or we may not be able to sell such products profitably.

We and our collaborating partners may be subject, directly or indirectly, to federal and state healthcare fraud and abuse and false claims laws and regulations. If we or our collaborating partners are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

All marketing activities associated with drug products that are approved for sale in the United States, if any, will be, directly or indirectly through our customers, subject to numerous federal and state laws governing the marketing and promotion of pharmaceutical products in the United States, including, without limitation, the federal Anti-Kickback Law, the federal False Claims Act and HIPAA. These laws may adversely impact, among other things, our proposed sales, marketing and education programs.

The federal Anti-Kickback Law prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of co-payments and deductibles, ownership interests and providing anything at less than its fair market value. Despite a series of narrow safe harbors, the federal Anti-Kickback Law prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Penalties for violations of the federal Anti-Kickback Law include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other state or federal healthcare programs. Many states have also adopted laws similar to the federal Anti-Kickback Law, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

The federal False Claims Act imposes liability on any person who, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. In addition, various states have enacted false claims laws analogous to the False Claims Act. Many of these state laws apply where a claim is submitted to any third-party payer and not merely a federal healthcare program. Violations of the federal False Claims Act and the analogous state laws may result in substantial financial penalties, some as much as three times the actual damages sustained by the government.

HIPAA created several new federal crimes, including health care fraud, and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

We are unable to predict whether we could be subject to actions under any of these or other fraud and abuse laws, or the impact of such actions. Moreover, to the extent that taliglucerase alfa or any of our product candidates, if approved for marketing, will be sold in a foreign country, we and our future collaborators may be subject to similar foreign laws and regulations. If we or any of our future collaborators are found to be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring or our operations, any of which could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Intellectual Property Matters

The intellectual property and assets owned by our subsidiaries are subject to security agreements that secure our payment and other obligations under our 2021 Notes, and our subsidiaries have guaranteed all of those obligations.

In connection with the issuance of our 2021 Notes, we entered into security agreements pursuant to which our subsidiaries provided first priority security interests in all of their assets, which consist of all of our intellectual property and other material assets. The security agreements secure certain payment, indemnification and other obligations under the 2021 Notes. If we were to default on certain of our obligations, or in certain other circumstances generally related to a bankruptcy or insolvency, holders of our outstanding 2021 Notes could seek to foreclose on the collateral under the security agreements to obtain satisfaction of our obligations, and our business could be materially and adversely impacted, which would in turn have a material adverse effect on our results of operations and financial condition.

Furthermore, in connection with the issuance of the 2021 Notes, our subsidiaries guaranteed all of our obligations under the indenture governing such convertible notes. If we were to default on our obligations under the indenture, the holders could require our subsidiaries to satisfy all of those obligations under the guarantees.

If we fail to adequately protect or enforce our intellectual property rights or secure rights to third party patents, the value of our intellectual property rights would diminish and our business, competitive position and results of operations would suffer.

As of March 31, 2021, we had more than 35 pending patent applications of which two are joint pending patent applications with a third party. However, the filing of a patent application does not mean that we will be issued a patent, or that any patent eventually issued will be as broad as requested in the patent application or sufficient to protect our technology. Any modification required to a current patent application may delay the approval of such patent application which would have a material adverse effect on our business, results of operations and financial condition. In addition, there are a number of factors that could cause our patents, if granted, to become invalid or unenforceable or that could cause our patent applications to not be granted, including known or unknown prior art, deficiencies in the patent application or the lack of originality of the technology. Our competitive position and future revenues will depend in part on our ability and the ability of our licensors and collaborators to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing the proprietary rights of third parties. We have filed U.S. and international patent applications for process patents, as well as composition of matter patents, for taliglucerase alfa and our product candidates. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors and those who infringe upon our patents, including whether third parties will find ways to invalidate or otherwise circumvent our licensed patents;
- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our licensed patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings, which may be costly, whether we win or lose.

As of March 31, 2021, we held, or had license rights to, more than 90 patents. If patent rights covering our products or technologies are not sufficiently broad, they may not provide us with sufficient proprietary protection or competitive advantages against competitors with similar products and technologies. Furthermore, if the USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or circumvent the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from or to third parties may not provide any protection against our competitors and those who infringe upon our patents.

Furthermore, the life of our patents is limited. The patents we hold, and the patents that may be issued in the future based on patent applications from the patent families, relating to our ProCellEx protein expression system are expected to expire by 2025.

We rely on confidentiality agreements that could be breached and may be difficult to enforce which could have a material adverse effect on our business and competitive position.

Our policy is to enter agreements relating to the non-disclosure of confidential information with third parties, including our contractors, consultants, advisors and research collaborators, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. However, these agreements can be difficult and costly to enforce. Moreover, to the extent that our contractors, consultants, advisors and research collaborators apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to the intellectual property. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors and others. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach; or
- our trade secrets or proprietary know-how will otherwise become known.

Any breach of our confidentiality agreements or our failure to effectively enforce such agreements may have a material adverse effect on our business and competitive position.

If we infringe the rights of third parties we could be prevented from selling products, forced to pay damages and required to defend against litigation which could result in substantial costs and may have a material adverse effect on our business, results of operations and financial condition.

We have not received to date any claims of infringement by any third parties. However, as our drug candidates progress into clinical trials and commercialization, if at all, our public profile and that of our drug candidates may be raised and generate such claims. Defending against such claims, and occurrence of a judgment adverse to us, could result in unanticipated costs and may have a material adverse effect on our business and competitive position. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we may incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others, which could cause us to lose the use of one or more of our drug candidates;
- defend litigation or administrative proceedings that may be costly whether we win or lose, and which could result in a substantial diversion of management resources; or
- pay damages.

Any costs incurred in connection with such events or the inability to sell our products may have a material adverse effect on our business, results of operations and financial condition.

If we cannot meet requirements under our license agreements, we could lose the rights to our products, which could have a material adverse effect on our business.

We depend on licensing agreements with third parties to maintain the intellectual property rights to certain of our product candidates. Our license agreements require us to make payments and satisfy performance obligations in order to maintain our rights under these agreements. All of these agreements last either throughout the life of the patents that are the subject of the agreements, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology which could have a material adverse effect on our business, results of operations and financial condition.

Risks Relating to our Operations in Israel

Potential political, economic and military instability in the State of Israel, where the majority of our senior management and our research and development facilities are located, may adversely affect our results of operations.

Our executive office and operations are located in the State of Israel. Accordingly, political, economic and military conditions in Israel directly affect our business. Since the State of Israel was established in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could affect adversely our operations and product development. Although Israel has entered into various agreements with Egypt, Jordan and the Palestinian Authority, Israel periodically experiences an increase in unrest and terrorist activity. The establishment in 2006 of a government in the Gaza Strip by representatives of the Hamas militant group has created additional unrest and uncertainty in the region. Our facilities in northern Israel are in range of rockets that were fired from Lebanon into Israel during a 2006 war with the Hizbollah in Lebanon, and suffered minimal damages during one of the rocket attacks. Our insurance policies do not cover us for the damages incurred in connection with these conflicts or for any resulting disruption in our operations. The Israeli government, as a matter of law, provides coverage for the reinstatement value of direct damages that are caused by terrorist attacks or acts of war; however, the government may cease providing such coverage or the coverage might not be enough to cover potential damages. If our facilities are damaged as a result of hostile action, our operations may be materially adversely affected.

There is currently a civil war in Syria, also bordering Israel, and Israel has been hit by rockets and mortars originating from Syria. The ultimate effect of these developments on the political and security situation in the Middle East and on Israel’s position within the region is not clear at this time.

Our operations may be disrupted by the obligations of our personnel to perform military service which could have a material adverse effect on our business.

Many of our male employees in Israel, including members of senior management, are obligated to perform up to one month (in some cases more) of annual military reserve duty until they reach the age of 45 and, in the event of a military conflict, could be called to active duty. Our operations could be disrupted by the absence of a significant number of our employees related to military service or the absence for extended periods of military service of one or more of our key employees. A disruption may have a material adverse effect on our business, results of operations and financial condition.

Because a certain portion of our expenses is incurred in New Israeli Shekels, our results of operations may be seriously harmed by currency fluctuations and inflation.

We report our financial statements in U.S. dollars, our functional currency. Although most of our expenses are incurred in U.S. dollars, we pay a portion of our expenses in New Israeli Shekels, or NIS, and as a result, we are exposed to risk to the extent that the inflation rate in Israel exceeds the rate of devaluation of the NIS in relation to the U.S. dollar or if the timing of these devaluations lags behind inflation in Israel. In that event, the U.S. dollar cost of our operations in Israel will increase and our U.S. dollar-measured results of operations will be adversely affected. To the extent that the value of the NIS increases against the U.S. dollar, our expenses on a dollar cost basis increase. Our operations also could be adversely affected if we are unable to guard against currency fluctuations in the future. 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.

The tax benefits available to us require that we meet several conditions and may be terminated or reduced in the future, which would increase our taxes.

We are able to take advantage of tax exemptions and reductions resulting from the “Approved Enterprise” status of our facilities in Israel. To remain eligible for these tax benefits, we must continue to meet certain conditions, including making specified investments in property and equipment, and financing at least 30% of such investments with share capital. If we fail to meet these conditions in the future, the tax benefits would be canceled and we may be required to refund any tax benefits we already have enjoyed. These tax benefits are subject to investment policy by the Investment Center and may not be continued in the future at their current levels or at

any level. In recent years the Israeli government has reduced the benefits available and has indicated that it may further reduce or eliminate some of these benefits in the future. The termination or reduction of these tax benefits or our inability to qualify for additional "Approved Enterprise" approvals may increase our tax expenses in the future, which would reduce our expected profits and adversely affect our business and results of operations. Additionally, if we increase our activities outside of Israel, for example, by future acquisitions, such increased activities generally may not be eligible for inclusion in Israeli tax benefit programs.

The Israeli government grants we have received for certain research and development expenditures restrict our ability to manufacture products and transfer technologies outside of Israel and require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to refund grants previously received together with interest and penalties which could have a material adverse effect on our business and results of operations.

Our research and development efforts have been financed, in part, through grants that we have received from NATI. We, therefore, must comply with the requirements of the Research Law. Under the Research Law we are prohibited from manufacturing products developed using these grants outside of the State of Israel without special approvals, although the Research Law does enable companies to seek prior approval for conducting manufacturing activities outside of Israel without being subject to increased royalties. We may not receive the required approvals for any proposed transfer of manufacturing activities. Even if we do receive approval to manufacture products developed with government grants outside of Israel, we may be required to pay an increased total amount of royalties (possibly up to 300% of the grant amounts plus interest), depending on the manufacturing volume that is performed outside of Israel, as well as at a possibly increased royalty rate. This restriction may impair our ability to outsource manufacturing or engage in similar arrangements for those products or technologies.

Additionally, under the Research Law, Protalix Ltd. is prohibited from transferring NATI-financed technologies and related intellectual property rights outside of the State of Israel, except under limited circumstances and only with the approval of NATI Council or the Research Committee. Protalix Ltd. may not receive the required approvals for any proposed transfer and, if received, Protalix Ltd. may be required to pay NATI a portion of the consideration that it receives upon any sale of such technology by a non-Israeli entity. The scope of the support received, the royalties that Protalix Ltd. has already paid to NATI, the amount of time that has elapsed between the date on which the know-how was transferred and the date on which NATI grants were received and the sale price and the form of transaction will be taken into account in order to calculate the amount of the payment to NATI. Approval of the transfer of technology to residents of the State of Israel is required, and may be granted in specific circumstances only if the recipient abides by the provisions of applicable laws, including the restrictions on the transfer of know-how and the obligation to pay royalties. No assurance can be made that approval to any such transfer, if requested, will be granted.

These restrictions may impair our ability to sell our technology assets or to outsource manufacturing outside of Israel. The restrictions will continue to apply for a certain period of time even after we have repaid the full amount of royalties payable for the grants. For the years ended December 31, 2018, 2019 and 2020, we recorded grants totaling $2.2 million, $0.1 million and $0.1 million from NATI, respectively. The grants represent 6.2%, 0.2% and 0.2%, respectively, of our gross research and development expenditures for the years ended December 31, 2018, 2019 and 2020. If we fail to satisfy the conditions of the Research Law, we may be required to refund certain grants previously received together with interest and penalties, and may become subject to criminal charges, any of which could have a material adverse effect on our business, results of operations and financial condition.

Investors may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws against us, our executive officers and most of our directors or asserting U.S. securities laws claims in Israel.

Most of our directors and all of our executive officers are residents of Israel, and accordingly, most of their assets and our assets are located outside the United States. Service of process upon our non-U.S. resident directors and officers and enforcement of judgments obtained in the United States against us, some of our directors and executive officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that investors may find it difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws against us, our officers and our directors. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our officers and directors because Israel is not the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above.

Israeli courts might not enforce judgments rendered outside Israel which may make it difficult to collect on judgments rendered against us. Subject to certain time limitations, an Israeli court may declare a foreign civil judgment enforceable only if it finds that:

- the judgment was rendered by a court which was, according to the laws of the state of the court, competent to render the judgment;
- the judgment may no longer be appealed;
- the obligation imposed by the judgment is enforceable according to the rules relating to the enforceability of judgments in Israel and the substance of the judgment is not contrary to public policy; and
- the judgment is executory in the state in which it was given.

Even if these conditions are satisfied, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel. An Israeli court also will not declare a foreign judgment enforceable if:

- the judgment was obtained by fraud;
- there is a finding of lack of due process;
- the judgment was rendered by a court not competent to render it according to the laws of private international law in Israel;
- the judgment is at variance with another judgment that was given in the same matter between the same parties and that is still valid; or
- at the time the action was brought in the foreign court, a suit in the same matter and between the same parties was pending before a court or tribunal in Israel.

Risks Related to Investing in our Common Stock

The market price of our common stock may fluctuate significantly.*

The market price of our common stock has experienced significant volatility as a result of the recent announcement relating to the receipt of the CRL from the FDA regarding the BLA for PRX-102. The securities of life sciences companies often experience significant volatility in connection with clinical trial and regulatory announcements.

We anticipate that the market price of our common stock is likely to continue to fluctuate significantly in response to numerous factors, some of which are beyond our control, such as:

- our sale of shares of our common stock under our ATM program, or market expectations that such sales are to be executed;
- the timing of and any delays in anticipated marketing approvals for pegunigalsidase alfa;
- the progress and results of our ongoing studies regarding pegunigalsidase alfa and our other product candidates;
- announcements regarding partnerships or collaborations by us or our competitors;
- restatements of historical financial results and changes in financial forecasts;
- purchases of BioManguinhos alfataliglicerase in Brazil;
- developments concerning intellectual property rights and regulatory approvals;
- the announcement of new products or product enhancements by us or our competitors;

- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts;
- developments in the biotechnology industry; and
- general market conditions and other factors, including factors unrelated to our operating performance.

Continued market fluctuations could result in extreme volatility in the price of our common stock, which could cause a decline in the value of our common stock. Price volatility of our common stock may be worse when the trading volume of our common stock is low. We have not paid, and do not expect to pay, any cash dividends on our common stock as any earnings generated from future operations will be used to finance our operations. As a result, investors will not realize any income from an investment in our common stock until and unless their shares are sold at a profit.

Future sales of our common stock could reduce our stock price.

If our stockholders sell substantial amounts of our common stock, including shares of our common stock issuable upon conversion of our outstanding convertible notes or warrants, or if we sell a substantial amount of our common stock under our ATM program, the market price of our common stock could decrease significantly. The perception in the public market that our existing stockholders might sell shares of common stock could also depress the trading price of our common stock.

A substantial majority of our outstanding shares of our common stock are freely tradable without restriction or further registration under the federal securities laws. In addition, we may sell additional shares of our common stock in the future to raise capital. A substantial number of shares of our common stock are reserved for issuance upon the exercise of stock options, upon conversion of our outstanding convertible notes and upon the exercise of our outstanding warrants. At March 31, 2021, there were outstanding options to purchase common stock issued covering approximately 2.6 million shares of our common stock with a weighted average exercise price of approximately $5.30 per share. Also at March 31, 2021, there were approximately 1.5 million shares of common stock available for future for issuance in connection with future grants of incentives under our amended 2006 stock incentive plan, approximately 6.8 million shares of common stock reserved for issuance upon conversion of our outstanding 2021 Notes and approximately 17.4 million shares of common stock reserved for issuance upon the exercise of our outstanding warrants. The issuance and sale of substantial amounts of common stock, or the perception that such issuances and sales may occur, could adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

If securities analysts stop publishing research or reports about us or our business or if they downgrade our common stock, the market price of our common stock could decline.

The market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. We do not control these analysts. If any analyst who covers us downgrades our stock or lowers its future stock price targets or estimates of our operating results, the market price for our common stock could decline rapidly. Furthermore, if any analyst ceases to cover us, we could lose visibility in the market, which in turn could cause the market price of our common stock to decline.

Our common stock is listed to trade on more than one stock exchange, and this may result in price variations.

Our common stock is listed for trade on both the NYSE American and the TASE. Dual-listing may result in price variations between the exchanges due to a number of factors. First, our common stock is traded in U.S. dollars on the NYSE American and in NIS on the TASE. In addition, the exchanges are open for trade at different times of the day and on different days. For example, the TASE opens generally during Israeli business hours, Sunday through Thursday, while the NYSE American opens generally during U.S. business hours, Monday through Friday. The two exchanges also have differing vacation schedules. Differences in the trading schedules, as well as volatility in the exchange rate of the two currencies, among other factors, may result different trading prices for our common stock on the two exchanges. Other external influences may have different effects on the trading price of our common stock on the two exchanges.

Compliance with changing regulation of corporate governance and public disclosure may result in additional expenses, divert management's attention from operating our business which could have a material adverse effect on our business.

The laws, rules, regulations and standards including the rules promulgated by the national securities exchanges, including the NYSE American, to which we are subject are changed and/or amended from time to time. New or changed laws, rules, regulations and

standards are subject to varying interpretations in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, rules, regulations and standards are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. Members of our Board of Directors and our executive officers, could face an increased risk of personal liability in connection with the performance of their duties. As a result, we may have difficulty attracting and retaining qualified directors and executive officers, which could have a material adverse effect on our business. If our efforts to comply with new or changed laws, regulations and standards differ from the activities intended by regulatory or governing bodies, we may incur additional expenses to comply with standards set by regulatory authorities or governing bodies which would have a material adverse effect on our business, results of operations and financial condition.

The issuance of preferred stock or additional shares of common stock could adversely affect the rights of our stockholders.

Our Board of Directors is authorized to issue up to 100,000,000 shares of preferred stock without any further action on the part of our stockholders. Our Board of Directors has the authority to fix and determine the voting rights, rights of redemption and other rights and preferences of preferred stock. Currently, we have no shares of preferred stock outstanding.

Our Board of Directors may, at any time, authorize the issuance of a series of preferred stock that would grant to holders the preferred right to our assets upon liquidation, the right to receive dividend payments before dividends are distributed to the holders of common stock and the right to the redemption of the shares, together with a premium, before the redemption of our common stock, which may have a material adverse effect on the rights of the holders of our common stock. In addition, our Board of Directors, without further stockholder approval, may, at any time, issue large blocks of preferred stock. In addition, the ability of our Board of Directors to issue shares of preferred stock without any further action on the part of our stockholders may impede a takeover of our company and may prevent a transaction that is favorable to our stockholders.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed or Furnished Herewith
		Form	File Number	Exhibit	Date	
3.1	Certificate of Incorporation of the Company	8-K	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	Description of Capital Stock	10-K	001-33357	4.7	March 12, 2020	
4.8	Form of Warrant	8-K	001-33357	4.1	March 12, 2020	
4.9†	Form of Stock Option Agreement (Executives)	10-Q	001-33357	4.8	August 10, 2020	
4.10	Form of Stock Option Agreement (Standard)	10-Q	001-33357	4.9	August 10, 2020	
10.1††	Amended and Restated Agreement between Protalix Ltd. and Comercio e Serviços Ltda. dated June 17, 2013					X
10.2††	Technology Transfer and Supply Agreement made as of June 18, 2013 by and between Protalix Ltd. and Fundação Oswaldo Cruz					X
10.3††	Binding Term Sheet between Protalix Ltd. and Chiesi Farmaceutici S.p.A.					X
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).	

† Management contracts or compensation plans or arrangements in which directors or executive officers are eligible to participate.

†† Portions of this exhibit were omitted and have been filed separately with the Secretary of the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment under Rule 24b-2 of the Exchange Act.

SIGNATURES

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

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: May 14, 2021

By: /s/ Dror Bashan

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

Date: May 14, 2021

By: /s/ Eyal Rubin

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

Exhibit 10.1

Execution Version

[***] Represents material that has been omitted and will be filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

AGREEMENT

This Agreement is made and entered into on this 17 day of June, 2013

Between

PROTALIX LTD.

a company duly incorporated under the laws of Israel of 2 Snunit Street, Science Park, P.O. Box 455, Carmiel 20100, Israel

(**"Protalix"**)

and

ATME Comercio e Serviços Ltda.
a company duly incorporated under the laws of Brazil
of Alameda Tocantis, 75, room 1110, Alphaville, Barueri CEP 06455-020, Sao Paulo, Brazil

(**"ATME"**)

WHEREAS: Protalix and ATME entered into that certain May 2012 Agreement (the "**Original Agreement**") and this Agreement amends and restates in its entirety the Original Agreement.

WHEREAS: Protalix is engaged, *inter alia*, in the development, manufacture, marketing, distribution and sale, both on its own and together with Pfizer, Inc. ("**Pfizer**"), of a proprietary enzyme replacement therapy product for the treatment of Gaucher Disease based on taliglucerase alfa (the "**Product**"); and

WHEREAS Protalix and Pfizer entered into that certain Exclusive License and Supply Agreement, dated November 30, 2009 (the "**Original Pfizer Agreement**"), which is expected by Pfizer and Protalix to be amended by letter in 2013 to provide Protalix exclusive rights to commercialize the Product in the Territory (the "**Pfizer Amendment**", and the Original Pfizer Agreement, as amended by the Pfizer Amendment, the "**Pfizer Agreement**"); and

WHEREAS: Protalix is interested in penetrating the market for the Product(s) in Brazil (the "**Territory**") by way of sales of the Product(s) in the Territory and/or entering into a definitive transfer of technology and supply agreement with a manufacturer in, and for, the Territory; and

WHEREAS: ATME has the requisite knowledge, experience and expertise to assist Protalix in achieving its objectives for the Product(s) in the Brazilian market; and

WHEREAS: At Protalix's request and in furtherance of its aims, and based on the parties' understanding regarding mutually agreeable compensation of ATME if a successful transaction with respect to the Brazilian market were consummated, ATME applied such knowledge, experience and expertise to assist Protalix in its efforts to enter into a definitive agreement to supply the Product(s) to Fundacao Oswaldo Cruz, an agency of the Federal Brazilian Ministry of Health ("**Fiocruz**") for distribution and sale in the Brazilian market; and

WHEREAS: Such assistance from ATME has contributed to the success of such efforts by Protalix which is expected to result in the execution of a definitive Technology Transfer and Supply Agreement in 2013 by and between Protalix and Fiocruz (the "**2013 Contract**") and, together with all other agreements with FIOCRUZ that contain substantially the same economics of the 2013 Contract, (the "**Other Contract/s**") if any, entered into between Protalix and Fiocruz, within [***] years from the date of the 2013 Contract, for the transfer of technology with respect to, and the supply of, Product(s) to Fiocruz for distribution and sale in the Brazilian market, the "**Contracts**"); and

WHEREAS: The parties wish to confirm their understanding regarding the compensation by Protalix of ATME in consideration of such assistance and such contribution by ATME to Protalix's efforts and success in entering into, and the substantial economic benefits which may be realized by Protalix pursuant to, the Contracts (such assistance and contribution being sometimes referred to as the "**Services**").

NOW THEREFORE, it is agreed between the parties hereto that the Original Agreement is hereby amended and restated in its entirety to read as follows:

1. **Fees**

1.1. Upon the terms and subject to the conditions set forth herein, and in reliance on ATME's representations and warranties contained herein and in the Certification attached hereto as Exhibit A (the "**Certification**"), Protalix hereby agrees to pay ATME five percent (5%) of its Proceeds under the 2013 Contract and four percent (4%) of its Proceeds under the Other Contract/s (collectively, the "**Fees**"). For purposes of this Section, "**Proceeds**" shall mean the revenue for supply of Product(s) actually collected and recognized by Protalix from Fiocruz pursuant to the applicable Contract in accordance with US GAAP or any other accounting practice adopted by Protalix from time to time, after deduction of any commissions or royalties payable to third parties in respect to any activities under the applicable Contract and any amounts refunded for Product returns. For the avoidance of doubt, no (i) amounts paid to Protalix in reimbursement of expenses or for technical services performed pursuant to the applicable Contract; (ii) revenue collected or recognized by Protalix for Product supplied (or agreed to be supplied) at cost and not pursuant to Section 7 of the 2013 Contract (or any similar provision of any other Contract); or (iii) revenue collected or recognized by Protalix for Product supplied (or agreed to be supplied) prior to the date of this Agreement, shall be included in the definition of "**Proceeds**" under this Agreement. Notwithstanding the foregoing, in the event of a material change in the economic terms of the applicable Contract, the Parties will negotiate in good faith to adjust the Fees to reflect such change in economic terms.

1.2. The Fees constitute the sole and entire consideration and compensation which ATME is entitled to receive for the Services (and, except to the extent expressly agreed in writing by Protalix and ATME, any other services provided to Protalix by ATME, or any employee or principal thereof, to the extent related to the Product(s) in the Territory). Protalix shall not be required to reimburse ATME for any costs or expenses incurred by ATME in connection with this Agreement, the Services or otherwise, all of which shall be ATME's sole responsibility.

2. **Terms of Payment**

2.1. Payment of Fees, if any shall have become payable, shall be made within [***] after Protalix receipt of any payment from FIOCRUZ with respect to Proceeds. Protalix shall provide ATME with a quarterly report which shall set forth the amount of Proceeds in respect of the preceding quarter.

2.2. The Fees shall be paid in the same currency as the Proceeds and shall be inclusive of all sales and other taxes and fees, which shall be borne by ATME.

2.3. If Protalix is required by applicable law to make any tax deduction, tax withholding or similar payment or withholding from any amount paid or payable by Protalix hereunder, including but not limited to on account of income tax, tax on profit or any other taxes or fees imposed on ATME ("**Withholding Tax**"), then Protalix shall notify ATME of this requirement and shall deduct the Withholding Tax from the payments referred to above, as prescribed by applicable law and shall not be required to "gross-up" or otherwise increase any such payments to accommodate for such Withholding Tax.

[***] Redacted pursuant to confidential treatment request.

2.4. Notwithstanding anything to the contrary herein, Protalix shall be obligated to pay the Fees only (i) after ATME has obtained and secured all consents, permits, licenses and approvals, if any, required in connection with the execution, delivery, performance, validity and enforceability of this Agreement, and provided copies thereof to Protalix, [***].

3. **Termination**

(a) This Agreement (i) shall automatically terminate (with respect to the applicable Contract, or as a whole if in relation to all existing Contracts) upon the termination of the applicable Contract for any reason and (ii) may be terminated by Protalix by notice to ATME if the representation or warranty of ATME in Section 7.2.3, 7.2.4 or 7.2.5 shall have been or be inaccurate in any material respect or ATME shall have failed to perform or comply in any material respect with any covenant of ATME contained herein

(b) Without limiting the generality of paragraph 3(a) and for the avoidance of doubt, Protalix may terminate this Agreement, effective immediately upon notice by Protalix to ATME, if (i) Protalix determines, based on information from sources it reasonably believes are credible, that any representation, warranty or other statement contained in the Certification is inaccurate in any material respect or (ii) ATME shall have failed to perform or comply in any material respect with any covenant or agreement of ATME set forth in the Certification.

(c) Upon termination of this Agreement in accordance with its terms, all rights and duties of the parties hereunder shall cease, except that (i) ATME shall be entitled to payment of Fees in accordance with the provisions of Section 3 above to the extent such Fees became payable prior to the effective date of termination and provided such termination was not pursuant to clause (ii) of paragraph (a) or pursuant to paragraph (b) of this Section 3, (ii) the provisions of Section 4 below shall survive any such termination and (iii) such termination shall not relieve a party from liability for breach prior to such termination of any representation, warranty, covenant or agreement set forth herein.

4. **Confidentiality**

ATME acknowledges that proprietary and/or confidential information of Protalix and/or Pfizer and/or relating to the Product(s), this Agreement and/or any Contract (including, without limitation, information relating to the business, operations, research and development activities, products, technology or other intellectual property of Protalix or Pfizer) may have been obtained by or disclosed to ATME in the course of, for the purpose of, or otherwise in connection with, the performance (or anticipated performance) of, the Services, whether orally, in writing, electronically or in any other form, and whether obtained or disclosed prior to or during the Term (collectively, the "**Confidential Information**").

ATME agrees to keep the Confidential Information and the terms of this Agreement and the Contracts in strict confidence and ATME shall not, without the prior written consent of Protalix, disclose such information to any third party. Upon the termination of this Agreement for any reason or upon request by Protalix, ATME shall promptly return to Protalix (or, at Protalix's option, destroy) any and all Confidential Information and any and all manifestations and copies of the Confidential Information in the possession or control of ATME. The provisions of this Section 4 shall survive any expiration or termination of this Agreement.

5. **Independent Contractor**

ATME has been, is and shall remain at all times an independent contractor for all purposes (including, but not limited to employee benefits, unemployment benefits, income tax withholding, health and other insurance), and is not, and shall not represent itself as, the agent, partner, officer or employee of Protalix. The Parties acknowledge and agree that ATME has assisted Protalix only in relation to the Contracts and has not been appointed an agent of Protalix, as defined under the Brazilian Agency Law or any other applicable law, and, therefore, is not entitled to any benefits, payments, protections or indemnities established by any such laws.

For the removal of doubt, ATME has had, currently has, and shall have, no authority to bind or commit Protalix by or to any contract or otherwise.

[***] Redacted pursuant to confidential treatment request.

6. **Costs and Expenses**

Each party shall bear all of its own costs and expenses incurred both directly or indirectly as a result of performing its obligations under this Agreement.

7. **Additional Representations, Warranties and Covenants of ATME**

7.1. ATME acknowledges that it has been advised that Protalix is a party to the Pfizer Agreement which addresses, *inter alia*, Protalix's rights to register, manufacture, market, distribute and sell the Product in the Territory, and that it is subject to certain restrictions thereunder. ATME hereby represents and warrants to Protalix, and covenants with Protalix, that it shall not have any claim against Protalix, of any nature, in respect of the exercise, by Pfizer, of its rights under the Pfizer Agreement, regardless of whether ATME was previously informed of such rights or not;

7.2. ATME hereby further represents and warrants to Protalix, and covenants with Protalix, that

7.2.1. it does not have any pre-existing obligations that are inconsistent with this Agreement;

7.2.2. so long as ATME remains entitled to receive Fees hereunder, it shall not render services to any other person or entity to facilitate, directly or indirectly, the promotion, marketing or sale in Brazil of any product for the treatment of Gaucher Disease or any other Product covered under any Contract.

7.2.3. in its performance of the Services and otherwise in connection with its activities, communications and other conduct relating, directly or indirectly, to any Contract or this Agreement, it has complied, and shall comply, with all, and has not taken and shall not take any action that would cause Protalix to violate any, (i) applicable laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977 (the "**FCPA**"), including but not limited to acquiring and maintaining any consents, permits, licenses and approvals and fulfilling any reporting requirements which may be applicable to the Services or this Agreement, in the Territory, and (ii) of Pfizer's Anti-Bribery and Anti-Corruption Principles set forth on Appendix 10.1(t) of the Pfizer Agreement, a copy of which is attached hereto as Exhibit B (for this purpose substituting throughout such document "Protalix" for "Pfizer" in each place that the word "Pfizer" appears (the "**Principles**"));

7.2.4. the representations, warranties and other statements contained in the Certification are true and correct, and ATME has performed and complied, and will perform and comply, with the covenants and agreements of ATME set forth therein.

7.2.5. it has not employed or utilized as a subcontractor or otherwise, does not currently employ or utilize as a subcontractor or otherwise, and will not employ or utilize as a subcontractor or otherwise, any person that has been debarred or has otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the ANVISA or any other Governmental Authority or professional body with respect to the performance of scientific or clinical investigations, or any person finally convicted of a criminal offense, with no existing rights to appeal such conviction, in relation to: (i) the development or approval (including the process for development or approval) of an abbreviated drug application; (ii) the development or approval of any drug product or otherwise relating to the regulation of any drug product; or (iii) bribery payment of illegal gratuities, fraud, perjury, racketeering, blackmail, extortion, falsification or destruction of records or interference with, obstructions of an investigation into a prosecution of any criminal offense; and

7.2.6. [***]

7.2.7. Protalix will allow ATME or independent accounting firm or law firm designated by Protalix, periodic, but not less than annually, access to Protalix's relevant books and records for the purpose of confirming the accuracy of the quarterly reports provided by Protalix to ATME hereunder.

[***] Redacted pursuant to confidential treatment request.

7.3. ATME shall provide Protalix with an updated executed copy of the Certification annually for five (5) years after the execution of the 2013 Contract.

7.4. [***]

8. **Pfizer Indemnification Agreement; Indemnification of Protalix**

8.1. ATME hereby agrees that neither ATME nor [***] and/or any of their affiliates, principals, officers, directors, employees, owners, family members, agents, contractors, or consultants, whether such persons are acting independently or as agents of [***] and/or ATME (each such person or entity, together with [***] and/or ATME, an "**ATME Person**") will assert any claims against Pfizer for which Protalix has indemnified Pfizer pursuant to Protalix's agreement to indemnify Pfizer against any claims asserted by any ATME Person and certain other claims relating to Protalix's relationship and interactions with ATME (the "**Pfizer Indemnification**").

8.2. ATME shall indemnify, defend and hold Protalix and its affiliates, and their respective directors, officers, shareholders, representatives, agents, successors, assigns, licensors and employees harmless from and against all liability, claims, losses, damages, causes of actions, and costs and expenses (including reasonable attorney's fees) resulting from or arising out of (a) any acts or omissions of ATME in connection with ATME's performance of the Services, (b) the inaccuracy or breach of any representation, warranty, covenant or agreement made by ATME in this Agreement or in the Certification or the Principles, (c) any acts or omissions of ATME or of any principal, owner, affiliate, officer, director, employee, contractor, consultant or agent of ATME that are inconsistent with ATME's agreement not to assert claims against Pfizer set forth in Section 8.1 above, (d) any inquiry, investigation, litigation or proceeding by a governmental authority or third party regarding any ATME Person in connection with the commercialization of the Product in Brazil by Protalix, any Contract, or any other actions of an ATME Person on behalf of Protalix, or (e) any amounts Protalix is required to pay to Pfizer under the Pfizer Indemnification. The provisions of this Section 8 shall survive any termination of this Agreement.

9. **Notices**

Except as otherwise provided in this Agreement, all notices permitted or required by this Agreement shall be in writing and shall be deemed to have been duly served (i) if personally delivered, when actually delivered; (ii) if sent by facsimile, upon transmission thereof (receipt of which has been orally confirmed by the recipient); or (iii) 7 (seven) business days after being mailed, postage prepaid, return receipt requested, if sent by registered mail and addressed to the address of the parties set out below or in accordance with such other address information as the party to receive notice may provide in writing to the other party in accordance with the above notice provisions.

If to Protalix:

Protalix Ltd.
2 Snunit Street Science Park
P.O. Box 455
Carmiel 20100
Israel
Facsimile: + 972-4-988-8092
Attention: Dr David Aviezer CEO

If to ATME:

ATME Comercio e Serviços Ltda.
Alameda Tocantes, 75
Alphaville, Barueri, CEP 06455-020
Sao Paulo Brazil
Facsimile: +55.11-4195-6621
Attention: Abraham Meizler

[***] Redacted pursuant to confidential treatment request.

10. **Governing Law and Jurisdiction**

This Agreement shall be governed by and construed in accordance with the laws of Israel, without giving effect to its principles of conflicts of law that direct that the laws of another jurisdiction apply and the parties hereto hereby submit to the exclusive jurisdiction of the competent courts in Tel-Aviv- Jaffa. Notwithstanding the foregoing, Protalix may apply to any court of competent jurisdiction in Brazil or any other applicable jurisdiction for injunctive or other equitable relief or to enforce any judgment obtained against ATME in connection with this Agreement.

11. **Entire Agreement; Amendments**

This Agreement constitutes the entire agreement between the parties hereto in respect of their Product-related collaboration in the Territory, and supersedes all prior agreements or understandings between the parties relating to the subject-matter hereof. This Agreement may only be amended by a written document signed by both of the parties to this Agreement. This Agreement shall be binding on and inure to the benefit of the parties hereto and their respective successors and permitted assigns.

12. **Assignment**

ATME is not entitled to assign or transfer this Agreement or any rights or obligations hereunder, without the prior written consent of Protalix which may be withheld in its sole and absolute discretion. Protalix shall have the right to assign its rights and obligations pursuant to this Agreement, in whole or in part, to Pfizer or any other party which may have an interest in the applicable Product; provided that it provides written notice to ATME following such assignment.

13. **Severability**

The provisions of this Agreement are severable and, in the event that any court of competent jurisdiction determines that any one or more of the provisions or part of a provision contained in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision or part of a provision of this Agreement.

14. **Waivers**

No waiver of any term of this Agreement shall be effective unless set forth in writing and duly executed by or on behalf of the party hereto waiving such term or condition. Neither the waiver of any term or condition of this Agreement, nor the failure to enforce or exercise any rights or remedies available under this Agreement, shall be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach of this Agreement. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

15. **Publicity**

ATME shall not make any press release or public statement (written or oral) concerning the terms of, or events related to, this Agreement or any Contract, or concerning the Services, Protalix, Pfizer, or the Product(s), without the prior written consent of Protalix which may be withheld in its sole and absolute discretion.

16. **Counterparts**

This Agreement may be executed in counterparts (including counterparts transmitted by facsimile), each of which shall be deemed to be an original, but which taken together shall be deemed to be an original and to constitute one and the same instrument .

[Intentionally left blank]

***IN WITNESS WHEREOF**, the parties hereto have caused this Agreement to be duly executed as of the date first aforementioned.*

PROTALIX LTD.	**ATME Comercio e Serviços Ltda.**
By: /s/ David Aviezer	By: /s/ Abraham Meizler
Name: David Aviezer	Name: Abraham Meizler
Title: CEO	Title: President/Partner
Date: June 18, 2013	Date: June 17, 2013

Exhibit A

Certification

[***]

[***] Redacted pursuant to confidential treatment request.

Exhibit B

Pfizer's Anti-Bribery and Anti-Corruption Principles

[***]

[***] Redacted pursuant to confidential treatment request.

Exhibit C

Training Completion Form

[***]

[***] Redacted pursuant to confidential treatment request.

[***] Represents material that has been omitted and will be filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

TECHNOLOGY TRANSFER AND SUPPLY AGREEMENT

This TECHNOLOGY TRANSFER AND SUPPLY AGREEMENT (this "AGREEMENT") is made as of _____ __, 2013 by and between **PROTALIX LTD.** , a limited liability company incorporated under the laws of Israel with offices located at 2 Snunit Street, Science Park, P.O.B 455, Carmiel 20100, Israel ("PROTALIX"), and **FUNDAÇÃO OSWALDO CRUZ** , an agency of the Brazilian Ministry of Health organized under the laws of Brazil, including its manufacturing unit "BIO-MANGUINHOS", with registered offices at Avenida Brasil, 4365, Manguinhos, Rio de Janeiro, RJ, Cep 21045-900, Brazil, CGC NI 33.781.055/0001-35, represented by its President, Dr. PAULO ERNANI GADELHA VIEIRA, hereinafter collectively referred to as "FIOCRUZ". For the purposes of this AGREEMENT, PROTALIX and FIOCRUZ each are referred to as a "PARTY" and collectively as the "PARTIES".

WHEREAS, PROTALIX owns or otherwise controls certain patents, patent applications, technology, know-how and scientific and technical information relating to an enzyme replacement therapy for the treatment of Gaucher Disease; and

WHEREAS, FIOCRUZ is a foundation affiliated with the Ministry of Health of the Brazilian Government and is a manufacturer of vaccines predominantly for the Brazil National Program of Immunization ("NPI") which owns, controls and operates Bio-Manguinhos;

WHEREAS, FIOCRUZ desires to obtain from PROTALIX, and PROTALIX desires to provide to FIOCRUZ, (i) the necessary rights and technical assistance and information, in various stages, to enable FIOCRUZ to MANUFACTURE and supply the Product in the Territory (as defined below), and (ii) the SUPPLIED MATERIALS (as defined below), pursuant to and in accordance with the terms of this AGREEMENT.

NOW, THEREFORE, in consideration of the premises, and the mutual covenants and agreements set forth herein, the PARTIES hereby agree as follows:

ARTICLE 1. DEFINITIONS

1.1For purposes of this AGREEMENT, the following terms shall have the meaning ascribed to such term herein:

[***]

"ADVISORY COMMITTEE" shall mean the committee organized and acting pursuant to Article 5.5 which shall have the overall responsibility for advising on and monitoring the implementation of the TECHNOLOGY TRANSFER up to and including the first successful production of the FINAL PRODUCT for commercial sale, pursuant to and in accordance with the terms and conditions of this AGREEMENT.

"AFFILIATE" means any entity directly or indirectly controlled by, controlling, or under common control with, a PARTY to this AGREEMENT, but only for so long as such control shall continue. For purposes of this definition, Article 12.3(d) and Article 20.6 only, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means (a) possession, direct or indirect, of the power to direct or cause direction of the management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of at least 50% of the voting securities or other ownership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity, it being understood and agreed that for purposes of clause (a), neither ownership of voting securities or other ownership interests of an entity nor membership or representation on (if less than half of the members of) an entity's board of directors shall, by themselves, be presumed to constitute the power to direct or cause direction of the management or policies of such entity. With respect to the grant of license or other rights by PROTALIX hereunder, "AFFILIATE" shall exclude any Third PARTY that becomes an Affiliate due to such Third PARTY's acquisition of PROTALIX or any other Person with an ownership interest in PROTALIX.

[***] Redacted pursuant to confidential treatment request.

“ANVISA” means the National Sanitary Surveillance Agency of the Brazilian Government (or any successor or replacement agency that has the authority to grant the necessary GOVERNMENTAL APPROVALS).

“BULK PRODUCT” means the DRUG SUBSTANCE component of a PRODUCT in liquid or frozen form.

“BUSINESS DAY” means a day other than a Saturday, Sunday, or bank or other public holiday in Brazil and/or Israel.

"CELL BANK" means a cell bank of vials with carrot cells producing *taliglucerase alfa* with information on its characterization and release, as well as information on its origin, plasmid, nature and sequence of the gene used, that is able to provide a sufficient number of vials for the production of the PRODUCT for a period time not less than 20 years.

“CERTIFICATE OF ACCEPTANCE” means a certificate in the form attached hereto as Appendix III, executed by PROTALIX and FIOCRUZ to confirm the COMPLETION of each STAGE.

“CHALLENGE” shall have the meaning ascribed to such term in Article 4.8.

“COMMERCIALIZATION” means the marketing, distribution, offering for sale, selling and importation of the PRODUCTS. When used as a verb, “ Commercialize ” means to engage in Commercialization.

“COMPOUND” means (a) a plant cell expressed recombinant Glucocerebrosidase enzyme having the sequence set forth in Exhibit A to this AGREEMENT, and (b) any analogs, derivatives and variants thereof.

“COMPLETION” means the completion of a STAGE after achieving the COMPLETION REQUIREMENTS of such STAGE, as confirmed by the ADVISORY COMMITTEE and the execution of the CERTIFICATE OF ACCEPTANCE by FIOCRUZ and PROTALIX, evidencing such completion.

“COMPLETION REQUIREMENTS” mean, in relation to each STAGE and the TECHNOLOGY TRANSFER as a whole, the corresponding requirements established in Article 5.2 and Appendix II for advancement to the next STAGE.

“CONFIDENTIAL INFORMATION” shall have the meaning ascribed to such term in Article 11.1.

“CONTROL” or “CONTROLLED” means, with respect to any compound, material, Technology, or intellectual property right, that a PARTY owns or has a license to use, commercialize, manufacture, market, distribute or sell, and has the ability to grant to the other PARTY access and/or a license or a sublicense (as applicable under this AGREEMENT) to such compound, material, Technology, or intellectual property right as provided for herein without violating (a) the terms of any agreement or other arrangements with any Third PARTY existing before or after the EXECUTION Date or (b) any LAW applicable to such license or sublicense.

“DISCLOSING PARTY” shall have the meaning ascribed to such term in Article 11.1.

“DRUG SUBSTANCE” means the Compound component of a pharmaceutical drug product.

“EFFECTIVE DATE” shall have the meaning ascribed to such term in Article 3.1.

“EXECUTION DATE” means the date on which the last PARTY signs this AGREEMENT so as to make it signed by each of the PARTIES.

“FACILITIES” means the facilities of FIOCRUZ in BIO-MANGUINHOS related to the PRODUCT, including the primary production facility, the secondary facilities and the quality control laboratories to be adequated or built and validated, maintained and operated by FIOCRUZ, solely, for each STAGE, after receipt by FIOCRUZ of written approval of PROTALIX following a full inspection of such facility to ensure such facility is acceptable for the purpose contemplated hereunder for such STAGE.

“FIELD” means enzyme replacement therapy for the treatment of Gaucher Disease for the approved indications, dosage forms and strengths.

“FILL/FINISH” means (a) formulating the Product using Drug Substance and required excipients, (b) filling the Product into vials, (c) lyophilization of the Drug Substance for incorporation into the Product, and (d) testing, including ongoing stability testing, and release

of the Product. For the avoidance of doubt, Fill/Finish shall not include any activities included in the definition of Labeling and Packaging.

“FINAL PRODUCT” shall mean PRODUCT produced entirely by FIOCRUZ at the FACILITIES from the CELL BANK.

“FINISHED PACKAGED PRODUCT” means the PRODUCT that has undergone FILL/FINISH and LABELING AND PACKAGING to be supplied by PROTALIX to FIOCRUZ until the registration of PRODUCT 2 by ANVISA in PROTALIX's or FIOCRUZ's name.

“FORCE MAJEURE EVENT” shall have the meaning ascribed to such term in Article 20.1.

“FORECAST” shall have the meaning ascribed to such term in Article 6.2.1.

“GOOD MANUFACTURING PRACTICES” or “GMP” means all applicable Good Manufacturing Practices including, (a) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in ANVISA RDC 17 and RDC 66-07 laying down the principals and guidelines of good manufacturing practice, (b) WHO GMP guidelines, and (c) the equivalent Laws in any relevant country or other sovereign entity in which PRODUCT is marketed, manufactured, distributed, offered for sale, sold or imported by or on behalf of FIOCRUZ, each as may be amended and applicable from time to time.

“GOVERNMENTAL AUTHORITY” means any court, agency, department, authority or other instrumentality of any national, state, country, city or other political subdivision.

“GOVERNMENTAL APPROVAL” means the authorizations and approvals (including regulatory and pricing approvals) of a Governmental Authority that are necessary for the TECHNOLOGY TRANSFER, or the COMMERCIALIZATION, MANUFACTURE, use or exploitation of the SUPPLIED MATERIALS, COMPOUND, DRUG SUBSTANCE or PRODUCTS in the TERRITORY.

“GOVERNMENT OFFICIAL” shall have the meaning ascribed to such term in Article 17.2(f).

“IMPROVEMENT” means any enhancements to the Protalix Technology enabling superior productivity, therapeutic activity, feasibility, profitability and/or improvement of the production processes included in the Protalix Technology.

“INDEMNIFIED PARTY” shall have the meaning ascribed to such term in Article 16.3.

“INDEMNIFYING PARTY” shall have the meaning ascribed to such term in Article 16.3.

"INITIAL FORECAST" shall have the meaning ascribed to such term in Article 6.2.1.

“INPI” means the Brazilian National Institute of Industrial Property.

“LABELING AND PACKAGING” means the final product labeling and packaging of the Product as intended for commercial distribution and sale of such PRODUCT to THIRD PARTIES in the TERRITORY, including insertion of materials such as patient inserts, patient medication guides, professional inserts and any other written, printed or graphic materials accompanying the Product.

“LAWS” means all laws, statutes, rules, regulations, codes, administrative or judicial orders, judgments, decrees, injunctions and/or ordinances of any Governmental Authority, and other legal requirements of any kind, whether currently in existence or hereafter promulgated, enacted, adopted or amended.

“LOSSES” means any and all damages (including all incidental, consequential, statutory and treble damages), awards, deficiencies, settlement amounts, defaults, assessments, fines, dues, penalties, costs, fees (including reasonable attorney fees), liabilities, obligations, taxes, liens, losses and expenses, including those incurred by or awarded to Third PARTIES with respect to a Third PARTY Claim by reason of any judgment, order, decree, stipulation or injunction, or any settlement entered into, and all other documented costs and expenses incurred in investigating, preparing or defending any Third PARTY Claim litigation or proceeding, commenced or threatened, or in complying with any judgments, orders, decrees, stipulations and injunctions (including court costs, interest and reasonable fees of attorneys, accountants and other experts).

“MANUFACTURE” or “MANUFACTURING” means all activities related to the manufacturing of the COMPOUND, Drug Substance or Products, and/or any ingredient thereof, including manufacturing for commercial sale, in-process and finished product testing, Fill/Finish, Labeling and Packaging, release of product, quality assurance activities related to manufacturing and release of product and ongoing stability tests and regulatory activities related to any of the foregoing.

“NAKED VIALS” means unlabelled vials [***] of PRODUCT that have undergone FILL/FINISH.

“NET SALES” means the gross receipts of all sales of FINAL PRODUCT by or on behalf of FIOCRUZ, less any sales taxes actually incurred and paid by FIOCRUZ and reasonable out-of-pocket costs of transportation insurance and transportation for such FINAL PRODUCT actually incurred and paid by FIOCRUZ. A Royalty Payment obligation shall accrue upon the receipt of payment for such FINAL Product.

[***]

"OCS" means the Office of the Chief Scientist of the Israeli Ministry of Trade, Industry and Labor.

“ORAL FORMULATION” means an oral formulation of a drug product for the treatment of Gaucher Disease which contains any Compound as the active pharmaceutical ingredient.

“PATENT APPLICATION” means any application for a Patent.

“PATENT RIGHTS” means Patents and Patent Applications.

“PATENTS” means issued patents, whether domestic or foreign, including issued patents granted with respect to all continuations, continuations-in-part, divisions, provisionals and renewals, patents of addition, supplementary protection certificates, registration or confirmation patents and all reissues, re-examination and extensions thereof.

“PERMITS” means all approvals, authorizations, stamps, registrations, clearances, consents, licenses, permits, certificates, or regulatory approvals of any Governmental Authority.

“PERSON” means an individual, corporation, partnership, company, joint venture, unincorporated organization, limited liability company or partnership, sole proprietorship, association, bank, trust company or trust, whether or not legal entities, or any Governmental Authority.

“PHARMACOVIGILANCE AGREEMENT” means the PHARMACOVIGILANCE Agreement(s) set forth as Appendix VIII, between PROTALIX and FIOCRUZ.

“PRICE” means the price to be charged by PROTALIX for SUPPLIED MATERIAL manufactured and supplied hereunder as delivered to FIOCRUZ, and which price is set forth in Article 6, herein.

“PRODUCT” means the pharmaceutical product *plant cell expressed recombinant Glucocerebrosidase* in any finished dosage form of a drug product that contains Drug Substance (excluding any ORAL FORMULATION), which is the object of the TECHNOLOGY TRANSFER under this AGREEMENT, and, as used in this AGREEMENT, refers to any one of PRODUCT 1, PRODUCT 2, PRODUCT 3 and FINAL PRODUCT (and PRODUCTS, as used in this AGREEMENT, refers to all of PRODUCT 1, PRODUCT 2, PRODUCT 3 and FINAL PRODUCT).

“PRODUCT 1” shall mean the FINISHED PACKAGED PRODUCT supplied to FIOCRUZ by PROTALIX.

"PRODUCT 2" shall mean PRODUCT LABELED AND PACKAGED by FIOCRUZ at the FACILITIES from NAKED VIALS supplied to FIOCRUZ by PROTALIX.

[***] Redacted pursuant to confidential treatment request.

“PRODUCT 3” shall mean PRODUCT FILLED/FINISHED and LABELED AND PACKAGED by FIOCRUZ at the FACILITIES from BULK PRODUCT supplied to FIOCRUZ by PROTALIX.

“PRODUCT MARKS” means the names and marks on the labeling and packaging of the FINISHED PACKAGED PRODUCTS supplied to FIOCRUZ hereunder by PROTALIX.

“PROTALIX PATENT RIGHTS” means all Patent Rights owned by PROTALIX or otherwise Controlled by PROTALIX as of the EFFECTIVE DATE or at any time during the Term that claim the composition of matter, MANUFACTURE or use of the Compound, Drug Substance or a drug product that contains Drug Substance, including the Patent Rights listed in Exhibit B.

“PROTALIX TECHNOLOGY” means any Technology possessed or otherwise Controlled by PROTALIX as of the EFFECTIVE DATE or at any time during Term 1 that is necessary for the MANUFACTURE of the PRODUCTS as MANUFACTURED by, on behalf of, or under license from, PROTALIX as of the EFFECTIVE DATE.

“PURCHASE ORDER” means a firm purchase order in written or electronic form submitted by FIOCRUZ in accordance with the terms of this Agreement to PROTALIX authorizing the manufacture and supply of SUPPLIED MATERIAL.

“RATE” shall have the meaning ascribed to such term in Article 9.4.

“RECIPIENT” shall have the meaning ascribed to such term in Article 11.1.

“REPORTING PERIOD” shall have the meaning ascribed to such term in Article 9.2.

“ROYALTY PAYMENTS” shall have the meaning ascribed to such term in Article 9.1.

“SPECIFICATIONS” means the specifications of the Drug Substance, PRODUCTS, and SUPPLIED MATERIALS designated by PROTALIX, as initially set forth in Appendix I, which may be updated from time to time by PROTALIX, including with respect to MANUFACTURING (including standard operating procedures for manufacturing), performance, quality control, release, and fill/finish specifications.

“STAGES” shall have the meaning ascribed to such term in Article 5.1.2.

“SUPPLIED MATERIALS” means the FINISHED PACKAGED PRODUCT, Naked Vials, Bulk Product and any other materials supplied to FIOCRUZ by PROTALIX for the MANUFACTURE and/or COMMERCIALIZATION by FIOCRUZ of PRODUCTS in the TERRITORY for the FIELD in accordance with this AGREEMENT.

“TECHNOLOGY” means all materials, technology, data, results and non-public technical, scientific and clinical information, in any tangible or intangible form, including know-how, expertise, trade secrets, practices, techniques, methods, processes, developments, specifications, formulations, formulae, and any intellectual property rights embodying any of the foregoing, but excluding any Patent Rights.

“TECHNOLOGY TRANSFER” means the provision to FIOCRUZ of the data and information comprising the Protalix Technology and the non-exclusive, non-transferable rights to use the Protalix Technology in the TERRITORY granted to FIOCRUZ hereunder), reasonably necessary to produce the PRODUCT, to be implemented in various stages as described in Article 5.2 and Appendix II of this AGREEMENT, for the sole purpose of enabling FIOCRUZ to MANUFACTURE the Products for sale within the Territory for the FIELD, and all data and documentation in PROTALIX's possession or control reasonably necessary for FIOCRUZ to obtain registration of the PRODUCTS by ANVISA, in accordance with and subject to the terms and conditions hereof.

“TERM” shall mean "TERM 1" and "TERM 2", and such terms shall have the meanings ascribed to such terms in Articles 12.1 and 12.2, respectively.

“THIRD PARTY” means any Person other than PROTALIX, FIOCRUZ or any of their respective Affiliates.

“THIRD PARTY CLAIM” shall have the meaning ascribed to such term in Article 16.3.

“THIRD PARTY LICENSE” means each license agreement between PROTALIX and a THIRD PARTY pursuant to which or from which PROTALIX obtains a license to PROTALIX TECHNOLOGY or PROTALIX PATENT RIGHTS.

“TERRITORY” means Brazil.

1.2 Except where expressly stated otherwise in this AGREEMENT, the following rules of interpretation apply to this AGREEMENT: (a) “include”, “includes” and “including” are not limiting and mean include, includes and including, without limitation; (b) definitions contained in this AGREEMENT are applicable to the singular as well as the plural forms of such terms; (c) references to an agreement, statute or instrument mean such agreement, statute or instrument as from time to time amended, modified or supplemented; (d) references to a Person are also to its permitted successors and assigns; (e) references to an “Article”, “Section”, “Exhibit”, “Appendix” or “Schedule” refer to an Article or Section of, or any Exhibit, Appendix or Schedule to, this AGREEMENT unless otherwise indicated; (f) the word “will” shall be construed to have the same meaning and effect as the word “shall”; and (g) the word “any” shall mean “any and all” unless otherwise indicated by context.

ARTICLE 2. AGREEMENT PURPOSE AND SCOPE

2.1 The primary purpose and scope of this AGREEMENT is the TECHNOLOGY TRANSFER from PROTALIX to FIOCRUZ in order to enable FIOCRUZ to produce and supply PRODUCTS in the TERRITORY for the FIELD, as follows:

(i) during the TECHNOLOGY TRANSFER, the sale and supply exclusively by PROTALIX to FIOCRUZ of the SUPPLIED MATERIALS for the purpose of FIOCRUZ manufacturing PRODUCTS in accordance with the STAGES and the provisions of Articles 5 and 6 in such quantities as provided herein, in order to satisfy the requirements of the Brazilian MOH for *plant cell expressed recombinant Glucocerebrosidase* during the period of the TECHNOLOGY TRANSFER and until registration of the FINAL PRODUCT by ANVISA in FIOCRUZ's name. For the avoidance of doubt, subject to Section 4.8, sales by FIOCRUZ outside of Brazil will only apply to FINAL PRODUCT and shall only take place after full completion of the TECHNOLOGY TRANSFER and in accordance with the terms and conditions of this AGREEMENT;

(ii) the supply of all of the, documentation and technical information reasonably necessary for the manufacturing and releasing of the PRODUCTS;

(iii) a non-exclusive, non-transferable and non-sublicensable license of Protalix Patent Rights in the TERRITORY for the term of such PATENTS in the TERRITORY, subject to the terms and conditions of this AGREEMENT; and

(iv) the provision of TECHNICAL ASSISTANCE by PROTALIX to FIOCRUZ.

ARTICLE 3. CONDITIONS PRECEDENT

3.1 This AGREEMENT shall become effective upon the last to occur of (a) the date of written notification by either PARTY to the other PARTY of approval by INPI of this AGREEMENT, (b) the date of written notification by either PARTY to the other PARTY of approval by OCS of this AGREEMENT, and (c) registration of the Product by ANVISA in the name of PROTALIX or, along with Laboratórios Pfizer Ltda.'s approval to import the PRODUCT into Brazil set forth on Appendix V, in the name of Laboratórios Pfizer Ltda. (the later of (a), (b) and (c), the “EFFECTIVE DATE”). If for any reason the supply of the FINISHED PACKAGED PRODUCT by PROTALIX to FIOCRUZ becomes prohibited under Brazilian LAW, notwithstanding anything to the contrary herein, PROTALIX shall not be required to supply such FINISHED PACKAGED PRODUCT for so long as such supply is prohibited and FIOCRUZ shall pay for any FINISHED PACKAGED PRODUCT already shipped to FIOCRUZ pursuant to the terms of this Agreement.

3.2 FIOCRUZ shall, at its sole cost and expense, submit this AGREEMENT to the INPI for approval and recordation (and take all other actions reasonably necessary to obtain such approval and recordation) promptly following the EXECUTION DATE and shall promptly notify PROTALIX of the approval and recordation of this AGREEMENT by INPI. PROTALIX shall, at its sole cost and expense, submit this AGREEMENT to the OCS for approval (and take all other actions reasonably necessary to obtain such approval) promptly following the EXECUTION DATE and shall promptly notify FIOCRUZ of the approval of this AGREEMENT by OCS.

ARTICLE 4. GRANT OF RIGHTS

4.1 Subject to the terms and conditions set forth herein, PROTALIX hereby grants to FIOCRUZ (a) the non-exclusive, non-transferable rights, as applicable, to use the Protalix Technology provided to FIOCRUZ hereunder, and (b) the non-exclusive, non-transferable and non-sublicensable license or sublicense, as applicable, under all PROTALIX PATENT RIGHTS in the TERRITORY for the duration of such Patent Rights, solely, with respect to the foregoing (a) and (b), for the purpose of MANUFACTURING PRODUCTS in the FACILITIES, and the COMMERCIALIZATION of such PRODUCTS, for sale within the Territory for the Field, as appropriate for each STAGE, in accordance with this AGREEMENT. Notwithstanding the foregoing, FIOCRUZ's right to COMMERCIALIZE the PRODUCTS in the TERRITORY for the FIELD shall be exclusive; provided that (x) such right shall become non-exclusive in the event that FIOCRUZ fails to comply with this Article 4.1 or Article 7.2 or is unable to meet demand for the PRODUCTS in the TERRITORY, and (y) shall not be exclusive with respect to any Protalix PATENTS RIGHTS or Protalix Technology that is subject to a THIRD PARTY LICENSE that does not provide PROTALIX the rights to grant exclusive sublicenses thereof. Any sublicense obligations required by a THIRD PARTY LICENSE to be included in a sublicense shall be deemed to be included in this AGREEMENT as obligations of FIOCRUZ [***].

4.2 FIOCRUZ shall not directly or indirectly market, promote, supply, distribute, offer for sale, or sell Products nor any other pharmaceutical product that contains DRUG SUBSTANCE or is derived from Protalix Technology or otherwise use or otherwise exploit the PROTALIX PATENTS RIGHTS, Protalix Technology, or SUPPLIED MATERIALS, in, for or to territories outside the TERRITORY or a field other than the Field, in connection with any other pharmaceutical products, or in any manner other than as expressly permitted hereunder.

4.3 FIOCRUZ shall not, without the prior written consent of PROTALIX directly or indirectly (a) disclose or otherwise make available the Protalix Technology, nor assign, transfer, license, or sublicense any rights obtained by FIOCRUZ hereunder, to any AFFILIATE or THIRD PARTY, (b) use the Protalix Technology for research or development, (c) MANUFACTURE or COMMERCIALIZE ProductS in any facility or plant other than the Facilities or through any unit of FIOCRUZ other than BIO-MANGUINHOS, nor (d) other than for the PRODUCTS, use the PROTALIX PATENTS RIGHTS or Protalix Technology in connection with any pharmaceutical products (including any successor or alternative delivery, presentations or dosing regimens of the Product).

4.4 During the Term, FIOCRUZ shall not directly or indirectly market, promote, supply, distribute, offer for sale, sell or otherwise exploit any other products that, in PROTALIX's good faith judgment may compete with the PRODUCT.

4.5 During the Technology Transfer, PROTALIX shall make available to FIOCRUZ all Improvements CONTROLLED by such PARTY that are useful to the MANUFACTURE of the PRODUCTS.

4.6 Except for the licenses and other rights granted to FIOCRUZ herein, all right, title and interest in and to the Protalix Patent Rights and Protalix Technology shall remain solely with PROTALIX and its licensors, as applicable.

[***] Redacted pursuant to confidential treatment request.

4.7 FIOCRUZ hereby covenants and agrees not to, directly or indirectly, commence (or assist any other Person in connection with) any claim, suit, action or other proceeding (including in front of any court or Governmental Authority, including any intellectual property office or registry), that challenges the legality, validity, enforceability, scope or ownership of any PROTALIX Patent Right or PROTALIX TECHNOLOGY (a "CHALLENGE"). If FIOCRUZ directly or indirectly commences (or assists any other Person in connection with) any Challenge, PROTALIX shall (a) have the right to immediately terminate this AGREEMENT by written notice effective upon receipt by FIOCRUZ, and (b) shall be entitled to recover from FIOCRUZ any and all costs and expenses, including reasonable attorneys' fees and expenses of investigation and defense, incurred by PROTALIX in connection with such Challenge.

4.8 Notwithstanding anything to the contrary herein, following COMPLETION of the TECHNOLOGY TRANSFER, [***].

4.9 For the avoidance of doubt, notwithstanding the license granted hereunder, PROTALIX shall retain its exclusive right in the TERRITORY to partner with patient advocacy groups, and provide patient support and medical education services to health care professionals, during the TERM and thereafter until COMPLETION of the TECHNOLOGY TRANSFER or for so long as PROTALIX continues to supply PRODUCTS to the TERRITORY.

4.10 From time to time throughout the TERM, PROTALIX will provide to FIOCRUZ information regarding the status of its development programs for the ORAL FORMULATION. Upon FIOCRUZ's reasonable request in writing (made no more than once per every twelve month period), PROTALIX agrees to discuss in good faith a possible collaboration with FIOCRUZ, or a license or sale to FIOCRUZ of rights, with respect to the ORAL FORMULATION. Any agreement resulting from such discussions relating to the ORAL FORMULATION (including any rights to be granted with respect to the ORAL FORMULATION) shall be separate and apart from this AGREEMENT. PROTALIX's obligations and FIOCRUZ's rights set forth in this Article 4.10 shall be PROTALIX's sole obligations and FIOCRUZ's sole rights hereunder with respect to the ORAL FORMULATION.

ARTICLE 5. TECHNOLOGY TRANSFER

5.1 General. The TECHNOLOGY TRANSFER shall commence upon the EFFECTIVE DATE and shall be implemented as set forth in the following chart (and as set forth in this Article 5 and Appendix II):

Estimated Time Table of Milestones in Product Production and Supply,
as a Result of Technology Transfer As Specified In Appendix II

Stages	Supplied by PROTALIX for PRODUCT supply	FIOCRUZ activity	Stages Quantity
Stage 0 - Immediately after the EFFECTIVE DATE	[***]	[***]	[***]
Stage 1 - Immediately after registration by ANVISA of PRODUCT 2 in FIOCRUZ's name	[***]	[***]	[***]
Stage 2 - After validation of FIOCRUZ new FILL AND FINISH facility	[***]	[***]	[***]
Stage 3 - After construction and validation of FIOCRUZ Plant Cell culturing facility and registration by ANVISA of FINAL PRODUCT in FIOCRUZ's name	[***]	[***]	[***]

TOTAL QUANTITY: [***] vials (or equivalent depending on PRODUCT type)

[***] Redacted pursuant to confidential treatment request.

Note: The FIOCRUZ activity set forth in each STAGE in the above chart (other than STAGE 0) shall only commence following the TECHNOLOGY TRANSFER by PROTALIX for, and the COMPLETION of, the prior STAGE, as set forth in Appendix II (so that FIOCRUZ is able to properly perform such activity). COMMERCIALIZATION of the FINAL PRODUCT shall only occur following COMPLETION of the TECHNOLOGY TRANSFER. During each STAGE, as applicable, PROTALIX shall use commercially reasonable efforts to provide, at FIOCRUZ's cost, any proprietary or non-commercial reagents and standards to FIOCRUZ that are required by FIOCRUZ in connection with its responsibilities for such STAGE, and use commercially reasonable efforts to help FIOCRUZ to become self-sufficient to produce or obtain such materials or reagents on its own.

5.1.1 Subject to the terms and conditions hereof, PROTALIX shall make available to FIOCRUZ at and for the FACILITIES, on a STAGE by STAGE basis, all Protalix Technology that is necessary for such STAGE and for the related MANUFACTURING, quality control and registration by ANVISA of the PRODUCTS by FIOCRUZ (including or as reasonable necessary for obtaining requisite GOVERNMENTAL APPROVALS) in accordance with this AGREEMENT. All PROTALIX TECHNOLOGY shall be provided in the English language. FIOCRUZ may translate any such documents at its own risk, cost and expense. Notwithstanding anything to the contrary herein, PROTALIX will transfer the PROTALIX TECHNOLOGY relating to [***] as the last step of STAGE 3 of the TECHNOLOGY TRANSFER only following positive completion by FIOCRUZ of clinical trials for the FINAL PRODUCT and registration by ANVISA of the FINAL PRODUCT in FIOCRUZ's name (as well as the other steps of STAGE 3 [***].

5.1.2 The PARTIES hereby agree that the TECHNOLOGY TRANSFER will be implemented in sequential stages (the “STAGES”) as set forth in Article 5.1, Article 5.2 and Appendix II. Each STAGE will take the time required to achieve the COMPLETION of such STAGE as provided by Article 5.2 and Appendix II. The beginning of each STAGE following STAGE 0 will be subject to the achievement of the COMPLETION REQUIREMENTS of the previous STAGE, as specified in Article 5.2 and Appendix II. FIOCRUZ will purchase the quantity of PRODUCTS set forth for each STAGE in the STAGES chart in Section 5.1, in order for COMPLETION of each such STAGE and commencement of the following STAGE (in addition to COMPLETING the other COMPLETION REQUIREMENTS), emphasizing that, notwithstanding anything to the contrary herein, proceeding to the STAGE 3 will only occur with the total purchase by FIOCRUZ of the estimated quantities for the STAGES 0, 1 and 2.

5.1.3 PROTALIX and FIOCRUZ shall each appoint, no later than thirty (30) calendar days after the EXECUTION DATE, its respective Technical Project Managers (whose duties are set forth in Articles 5.3 and 5.4 below) and prepare a coordination plan that will set forth and coordinate the activities of the PARTIES to take place during the period of the TECHNOLOGY TRANSFER. The coordination plan will take into account the contractual obligations of the PARTIES and shall include clauses such as addresses, correspondence, numbers, numbers of copies to be released, scheduling of activities, persons in charge, standards to be used for equipment and construction and other matters required or useful for the successful implementation of the TECHNOLOGY TRANSFER. Each of FIOCRUZ and PROTALIX shall notify the other in writing, at least thirty (30) days prior to replacing any of its Technical Project Managers and, in such case, shall cause both the replaced Technical Project Manager and the replacement Technical Project Manager to work together during a transition term of at least thirty (30) days.

5.1.4 During all STAGES, FIOCRUZ shall, at its own cost and expense, be responsible for (a) obtaining all GOVERNMENTAL APPROVALS required to MANUFACTURE and COMMERCIALIZE the PRODUCTS MANUFACTURED in the FACILITY in the Territory in accordance with the applicable STAGE, and (b) the construction, validation, maintenance and operation of the FACILITIES (including the new lyophilization suite, bioreactor facility and purification suites). FIOCRUZ shall be permitted to conduct any clinical trials approved by ANVISA required to obtain GOVERNMENTAL APPROVALS in the TERRITORY for the PRODUCTS entirely MANUFACTURED by FIOCRUZ at the FACILITY for the FIELD; provided FIOCRUZ provides PROTALIX prior written notice thereof and reasonably consults with PROTALIX upon PROTALIX’s request.

[***] Redacted pursuant to confidential treatment request.

5.1.5 Notwithstanding Article 5.1.4, and for the avoidance of doubt, (a) FIOCRUZ acknowledges and agrees that PROTALIX shall be permitted to obtain and maintain, and take all actions necessary to obtain and maintain its own GOVERNMENTAL APPROVALS for the PRODUCTS or similar pharmaceutical products in the TERRITORY, and (b) the PARTIES acknowledge and agree that until FIOCRUZ obtains its own GOVERNMENTAL APPROVAL for the Products, FIOCRUZ shall COMMERCIALIZE the FINISHED PACKAGED PRODUCT supplied by PROTALIX under the GOVERNMENTAL APPROVALS obtained prior to the Effective Date by PROTALIX for the Territory.

5.1.6 The purchase by and supply to FIOCRUZ of SUPPLIED MATERIALS during each STAGE of TECHNOLOGY TRANSFER shall occur in accordance with Article 6. As part of the TECHNOLOGY TRANSFER, PROTALIX may supply specific SUPPLIED MATERIALS to FIOCRUZ for the sole purpose of testing, validation and training, and for preparation for the following STAGE. FIOCRUZ shall utilize such SUPPLIED MATERIALS solely for such purpose and not for any commercial use.

5.2 STAGES. The TECHNOLOGY TRANSFER will be implemented in the sequential STAGES set forth in Appendix II, subject to and in accordance with the terms hereof, including Appendix II.

5.3 Responsibilities of PROTALIX. The sole obligations of PROTALIX relating to the TECHNOLOGY TRANSFER are set forth in this Article 5 and FIOCRUZ agrees that PROTALIX shall have no other obligations, express or implied, with respect thereto.

5.3.1 The PROTALIX Project Technical Manager will represent PROTALIX with respect to the implementation of the TECHNOLOGY TRANSFER. The PROTALIX Project Technical Manager will coordinate all activities of PROTALIX in relation to the TECHNOLOGY TRANSFER in cooperation with the FIOCRUZ Project Technical Manager. The PROTALIX Project Technical Manager shall not be responsible for the responsibilities of FIOCRUZ nor for management of FIOCRUZ’s employees or other personnel.

5.3.2 Following [***], in the event that FIOCRUZ's CELL BANK is damaged or otherwise becomes defective, PROTALIX shall utilize its own CELL BANK to provide a new CELL BANK to FIOCRUZ.

5.3.3 All of PROTALIX’s obligations under this Article 5 shall (a) be conditioned on FIOCRUZ’s cooperation in connection therewith and compliance with this AGREEMENT (including fulfillment of its responsibilities set forth in this Article 5), and (b) cease upon Completion of the final STAGE of the TECHNOLOGY TRANSFER.

5.4 Responsibilities of FIOCRUZ

5.4.1 The FIOCRUZ Project Technical Manager will represent FIOCRUZ with respect to the implementation of the TECHNOLOGY TRANSFER. The FIOCRUZ Project Technical Manager of FIOCRUZ will coordinate all activities of FIOCRUZ in relation to the TECHNOLOGY TRANSFER in cooperation with the PROTALIX Project Technical Manager. The FIOCRUZ Project Technical Manager shall not be responsible for the responsibilities of PROTALIX nor for management of PROTALIX’s employees or other personnel.

5.4.2 [***] in the event that PROTALIX's CELL BANK is damaged or otherwise becomes defective, FIOCRUZ shall utilize its own CELL BANK to provide a new CELL BANK to PROTALIX.

[***] Redacted pursuant to confidential treatment request.

5.4.3 FIOCRUZ shall take all necessary steps to ensure the FACILITY is constructed, maintained and operated in a manner that enables the safe and proper use of the PROTALIX TECHNOLOGY solely for the MANUFACTURE of the PRODUCTS in accordance with this AGREEMENT. FIOCRUZ will be responsible for the construction, validation, maintenance and operation of the FACILITIES during the term of this AGREEMENT and those FACILITIES shall at all times be (a) approved by ANVISA, (b) appropriate and adequate for implementing the then-current STAGE, and (c) in compliance with all the applicable LAWS, SPECIFICATIONS and GMP. The MANUFACTURING, COMMERCIALIZATION and storage operations, procedures and processes used by FIOCRUZ in connection with the MANUFACTURE of PRODUCTS hereunder (including any FACILITY) shall be in full compliance with all applicable SPECIFICATIONS and LAWS, including GMP and health and safety LAWS.

5.4.4 All costs and expenses related to the FACILITIES, including their construction, operation, maintenance and validation, shall be borne by FIOCRUZ. FIOCRUZ shall staff the FACILITIES with qualified personnel to perform all STAGES of the production and operation process and obtain the required GOVERNMENTAL APPROVALS therefor.

5.4.5 Except as otherwise expressly set forth herein, FIOCRUZ shall be responsible for the production and acquisition, at its own cost and expense, of all necessary materials. FIOCRUZ shall be responsible for the ensuring the quality of all such materials, including that such materials meet all requirements of applicable Brazilian LAWS.

5.5 ADVISORY COMMITTEE. PROTALIX and FIOCRUZ shall establish an ADVISORY COMMITTEE as of the EFFECTIVE DATE composed of three (3) senior members of each of PROTALIX and FIOCRUZ. The members of the ADVISORY COMMITTEE may be represented at any meeting by a designee appointed by such member for such meeting. The chairperson of the ADVISORY COMMITTEE shall be designated by PROTALIX. FIOCRUZ shall designate one of its representative members as secretary to the ADVISORY COMMITTEE. Each such PARTY shall be free to change its representative members by notice to the other such PARTY.

5.5.1 Responsibilities. The ADVISORY COMMITTEE shall be responsible for advising on and monitoring the implementation of the TECHNOLOGY TRANSFER, including clinical development work and regulatory activities in relation to PRODUCTS in a manner which is consistent with the terms and conditions of this AGREEMENT.

5.5.2 Meetings. The ADVISORY COMMITTEE shall meet at least twice every calendar year, (and more frequently should PROTALIX and FIOCRUZ agree to such more frequent meetings), on such dates and at such times as PROTALIX and FIOCRUZ shall agree. Additional meetings may also be called by either PROTALIX or FIOCRUZ as reasonably required, on forty (40) calendar days written notice to the other, unless such notice is waived by such other PARTY. The meetings shall alternate between the offices of PROTALIX and FIOCRUZ, unless the PARTIES otherwise agree. The chairperson shall be responsible for sending notices of meetings to all members. The ADVISORY COMMITTEE may also convene or be polled or consulted from time to time by means of telecommunications, video conferences or correspondence, as deemed necessary or appropriate. Fifteen (15) calendar days prior to each ADVISORY COMMITTEE meetings described above, an English summary of progress under the TECHNOLOGY TRANSFER shall be provided by FIOCRUZ to the members of the ADVISORY COMMITTEE, including detailed accounting of the expenditures.

5.5.3 Decisions. All decisions of the ADVISORY COMMITTEE shall be made by unanimous consent of the members present in person or by telephone or teleconferences/videoconferences at any meeting, with FIOCRUZ members cumulatively having one (1) vote and PROTALIX members cumulatively having one (1) vote. A quorum for a meeting shall require at least one (1) representative from FIOCRUZ and at least one (1) representative from PROTALIX.

5.5.4 In the event that unanimity cannot be reached by the ADVISORY COMMITTEE with respect to a matter that is subject to its decision-making authority, then the matter shall be referred for further review and resolution to the President of PROTALIX or such other similar position designated by PROTALIX from time to time, and the President of FIOCRUZ, or such other similar position designated by FIOCRUZ from time to time. The designated persons at each of PROTALIX and FIOCRUZ shall use reasonable efforts to resolve the matter within thirty (30) days after the matter is referred to them. In the event that the designated officers fail to resolve the matter during such time period, PROTALIX and FIOCRUZ agree to submit the matter to be resolved with the assistance of a suitably qualified independent mediator or expert. In the event that the matter is still not resolved within fifty (50) days after the matter was referred to the designated persons at each of PROTALIX and FIOCRUZ the proposal or

determination of PROTALIX's President shall prevail (provided such proposal or determination shall be made in good faith).

5.5.5 Minutes. Within fifteen (15) BUSINESS DAYS after each ADVISORY COMMITTEE meeting, the secretary of the ADVISORY COMMITTEE shall prepare and distribute minutes of the meeting, which shall provide a description in reasonable detail of the discussions held at that meeting and a list of any actions, decisions and/or determinations approved by the ADVISORY COMMITTEE. The secretary shall be responsible for circulation of all drafts and final minutes. Draft minutes shall be first circulated to the chairperson, edited and approved by the chairperson and then circulated in final draft form to all members of the ADVISORY COMMITTEE sufficiently in advance of the next meeting to allow adequate review and comment prior to the meeting. Minutes shall be approved or disapproved, and revised as necessary, at the next meeting. Final minutes shall be distributed to the members of the ADVISORY COMMITTEE.

5.5.6 Expenses. Each PARTY shall be responsible for all travel and related costs for its representatives to attend meetings of, and otherwise participate on, the ADVISORY COMMITTEE.

5.5.7 During the term of this AGREEMENT, the ADVISORY COMMITTEE shall be assisted by specific task forces ("TASK FORCES") which shall be responsible for advising the ADVISORY COMMITTEE within their area of responsibilities and implementing the decisions made by the ADVISORY COMMITTEE to the extent such decisions are within the competence of the TASK FORCES. The following TASK FORCES shall be organized:

(i) a technical TASK FORCE;

(ii) a clinical and regulatory TASK FORCE;

(iii) a manufacturing TASK FORCE; and

(iv) other TASK FORCES may be established upon the decision of the ADVISORY COMMITTEE.

The composition and numbers of representatives of each PARTY on each TASK FORCE shall be decided by both PROTALIX and FIOCRUZ on an ad hoc basis. Each of PROTALIX and FIOCRUZ shall be responsible for all travel and related costs for its representatives to attend TASK FORCE meetings.

ARTICLE 6. PURCHASE AND SUPPLY OF SUPPLIED MATERIALS

6.1 Agreement to Supply.

6.1.1 Commencing on the EFFECTIVE DATE and continuing until the COMPLETION of the TECHNOLOGY TRANSFER, PROTALIX will supply and FIOCRUZ will purchase SUPPLIED MATERIALS, in the form (e.g. , FINISHED PACKAGED PRODUCT, NAKED VIALS, BULK PRODUCT, etc.) appropriate for the then-current STAGE, that are necessary for FIOCRUZ to MANUFACTURE and/or COMMERCIALIZE the PRODUCTS in the TERRITORY for the FIELD, at the pricing set forth herein. [***]

6.1.2 Commercial supply will commence as soon as commercially reasonable, following the receipt of ANVISA approval for the PRODUCT.

6.1.3 Commencing on the EFFECTIVE DATE and continuing until the later of COMPLETION of the TECHNOLOGY TRANSFER, FIOCRUZ shall purchase the SUPPLIED MATERIALS from PROTALIX on an exclusive basis.

[***] Redacted pursuant to confidential treatment request.

6.1.4 During the TECHNOLOGY TRANSFER, if FIOCRUZ is unable to MANUFACTURE the PRODUCTS in accordance with the then-current STAGE, then FIOCRUZ shall, in accordance with this Article 6, submit to PROTALIX orders for, and PROTALIX shall use commercially reasonable efforts to fulfill such orders for, SUPPLIED MATERIALS in the form required by FIOCRUZ to MANUFACTURE and/or COMMERCIALIZE the PRODUCTS (e.g. , if, during STAGE 3, FIOCRUZ cannot adequately FILL/FINISH the BULK PRODUCT to create PRODUCTS, then PROTALIX shall use commercially reasonable efforts to supply [***] ordered by FIOCRUZ); provided that FIOCRUZ provides PROTALIX sixty (60) days advance notice thereof.

6.1.5 FINISHED PACKAGED PRODUCT will be provided with a minimum [***] remaining shelf life and NAKED VIALS will be provided with a minimum [***] remaining shelf life.

6.2 Forecasts and Purchase Orders.

6.2.1 On the EFFECTIVE DATE, or such later date that is at least ninety (90) days preceding the first requested delivery date for SUPPLIED MATERIALS, FIOCRUZ shall deliver to PROTALIX, FIOCRUZ's quarterly projection of the quantities of SUPPLIED MATERIALS that FIOCRUZ anticipates ordering from PROTALIX for the four (4) calendar quarters commencing with the first quarter that includes the first requested delivery date (the "INITIAL FORECAST"), together with a Purchase Order for SUPPLIED MATERIALS for the first two (2) calendar quarters covered by such Initial Forecast. The quantities of SUPPLIED MATERIALS specified for the remaining quarters of such Initial Forecast shall be non-binding. Thereafter, ninety (90) days prior to the first business day of each subsequent calendar quarter during the Term, FIOCRUZ shall deliver to PROTALIX a rolling four (4) calendar quarter forecast updating the prior forecast (together with the Initial Forecast, each a "FORECAST"), together with a Purchase Order for the first two (2) calendar quarters of such Forecast. The quantities of SUPPLIED MATERIALS specified for the remaining two (2) quarters of such Forecast shall be non-binding. Unless agreed separately between the PARTIES, each Purchase Order shall specify no more than three (3) delivery dates for the SUPPLIED MATERIALS in each calendar quarter. Purchase Orders shall be in writing, and no verbal communications or e-mail shall be construed to mean a commitment to purchase or sell. PROTALIX shall confirm receipt of any valid Purchase Order as soon as reasonably practicable after receipt. Subject to Sections 6.2.2, PROTALIX shall provide SUPPLIED MATERIALS to FIOCRUZ pursuant to valid Purchase Orders issued by FIOCRUZ to PROTALIX. FIOCRUZ shall provide PROTALIX with a written acknowledgment of receipt of SUPPLIED MATERIALS within three (3) BUSINESS DAYS of its receipt of SUPPLIED MATERIALS. This written acknowledgment shall confirm the quantity of SUPPLIED MATERIALS delivered and the date of delivery.

6.2.2 Unless otherwise agreed in writing by PROTALIX, in no event shall PROTALIX be obligated to deliver quantities of SUPPLIED MATERIALS specified in a Purchase Order for a quarter which exceed [***] of the quantities specified by FIOCRUZ for the same period in the Forecast delivered in the prior calendar quarter. PROTALIX shall, however, use commercially reasonable efforts, but will be under no obligation, to supply SUPPLIED MATERIALS in excess of [***] of such quantities specified in such Forecast. Without limitation to the foregoing, in no event shall PROTALIX be required to supply quantities of SUPPLIED MATERIALS in excess of those commercially reasonable for PROTALIX to supply for any given period.

6.2.3 Subject to Section 6.2.2, FIOCRUZ shall purchase all SUPPLIED MATERIALS ordered and specified in a Purchase Order. Purchase Orders may be delivered electronically or by other means to such location and in such manner as the PARTIES shall agree All Purchase Orders, confirmations of receipt of Purchase Orders and other notices contemplated under this Section 6.2 shall be sent to the attention of such persons as each party may identify to the other in writing from time to time in accordance with Section 20.9.

6.2.4 The Forecasts shall show demand for SUPPLIED MATERIALS on a monthly basis, and for the first three months of any such Forecast shall state the dates of required delivery for such SUPPLIED MATERIAL.

6.2.5 All Forecasts and Purchase Orders shall set forth the presentation of such SUPPLIED MATERIALS (e.g., FINISHED PACKAGED PRODUCT, NAKED VIALS, BULK PRODUCT).

[***] Redacted pursuant to confidential treatment request.

6.2.6 FIOCRUZ shall not submit Purchase Orders for, and PROTALIX shall not be required to supply, any single delivery of SUPPLIED MATERIALS of less than [***] of SUPPLIED MATERIALS (or the equivalent thereof with respect to DRUG SUBSTANCE). For the avoidance of doubt, all vials supplied hereunder shall be [***].

6.2.7 PROTALIX shall use commercially reasonable efforts to meet FIOCRUZ requests for additional quantities beyond those set forth in Purchase Orders.

6.3 Delivery; Risk of Loss.

6.3.1 PROTALIX shall ship SUPPLIED MATERIALS ordered by FIOCRUZ as set forth in the applicable Purchase Order, in accordance with the terms hereof. PROTALIX shall deliver SUPPLIED MATERIALS to FIOCRUZ by the delivery date set forth in the applicable Purchase Order, or such other date as may be agreed to in writing by the PARTIES from time to time. PROTALIX shall deliver SUPPLIED MATERIALS to FIOCRUZ FCA Protalix airport, customs cleared at shipping point, as per Incoterms 2000.

6.3.2 PROTALIX shall include certificates of analysis with all shipments of SUPPLIED MATERIAL.

6.3.3 Title to SUPPLIED MATERIAL shall pass to FIOCRUZ when the SUPPLIED MATERIAL has been delivered to FIOCRUZ pursuant to Article 6.3.1 above.

6.3.4 FIOCRUZ is responsible for acquiring import permits, letters of credit, customs clearance in Brazil and local transportation and distribution necessary for the supply and receipt of SUPPLIED MATERIALS to be supplied to FIOCRUZ hereunder.

6.4 Price; Payment; Taxes.

6.4.1 In the event the TECHNOLOGY TRANSFER is not COMPLETED by the end of the initial seven (7) year period, FIOCRUZ shall continue to obtain from PROTALIX its requirements of PROTALIX BULK PRODUCT for production of the PRODUCT at the same terms and conditions as described above and, for the renewal periods in TERM 1, PROTALIX shall provide [***]% discount over the last price of BULK PRODUCT as described in table below (6.4.2).

6.4.2 During TERM 1, the pricing for the SUPPLIED MATERIALS shall be as follows:

Year	**FINISHED PACKAGED PRODUCT PRICE** [***]	**NAKED VIALS PRICE** [***]	**BULK PRODUCT PRICE** [***]
From the EFFECTIVE DATE until one (1) year after the EFFECTIVE DATE.	[***]	[***]	[***]
From the end of the foregoing period until two (2) years after the EFFECTIVE DATE.	[***]	[***]	[***]
From the end of the foregoing period until three (3) years after the EFFECTIVE DATE.	[***]	[***]	[***]
From the end of the foregoing period until four (4) years after the EFFECTIVE DATE.	[***]	[***]	[***]
From the end of the foregoing period until five (5) years after the EFFECTIVE DATE.	[***]	[***]	[***]
From the end of the foregoing period until six (6) years after the EFFECTIVE DATE.	[***]	[***]	[***]
From the end of the foregoing period until the COMPLETION of the TECHNOLOGY TRANSFER	[***]	[***]	[***]

[***] Redacted pursuant to confidential treatment request.

6.4.3 Invoices and Payment. PROTALIX shall submit invoices to FIOCRUZ upon shipment of SUPPLIED MATERIALS to the address in the TERRITORY set forth in the applicable Purchase Order. FIOCRUZ shall pay all amounts due in U.S. Dollars within [***] from the date of receipt of the invoice by FIOCRUZ.

6.4.4 Taxes. Subject to Article 9.5 of this Agreement:

I. the Price includes all taxes except such sales, value-added and use taxes which PROTALIX is required by law to collect from FIOCRUZ;

II. such taxes, if any, will be separately stated in PROTALIX's invoice and will be paid by FIOCRUZ to PROTALIX, unless FIOCRUZ provides an exemption to PROTALIX, and subject to receipt of a valid receipt or invoice to FIOCRUZ in the form and manner required by LAW to allow FIOCRUZ to recover such taxes to the extent allowable by LAW; and

III. PROTALIX shall be solely responsible for the timely payment of all such taxes to the applicable GOVERNMENTAL AUTHORITY.

6.5 Purchase Order Effective Upon Anvisa Approval; Letter of Credit.

6.5.1 Notwithstanding anything to the contrary herein, (i) the PURCHASE ORDER set forth in Appendix IV for the first delivery, for [***], of PRODUCT for STAGE 0 of the Agreement shall be deemed to be delivered by FIOCRUZ to PROTALIX concurrently upon the EFFECTIVE DATE, and (ii) the PURCHASE ORDER for [***] of PRODUCT for completion of STAGE 0 of the AGREEMENT, shall be deemed to be delivered by FIOCRUZ to PROTALIX [***]. As security for payment of the PRICE for the PRODUCT to be ordered pursuant to such PURCHASER ORDER for the first delivery of STAGE 0, concurrently with the execution and delivery of this Agreement, FIOCRUZ shall execute and deliver to PROTALIX the letter of credit attached hereto as Appendix VI. For the avoidance of doubt, the quantity of PRODUCT purchased pursuant to such PURCHASE ORDER shall count towards and satisfy the first delivery requirement for STAGE 0 set forth in Section 5.1. As security for payment of the PRICE for the PRODUCT to be ordered pursuant to PURCHASE ORDERS, (a) concurrently with the execution and delivery of this AGREEMENT, FIOCRUZ shall request an irrevocable letter of credit to be confirmed by a first class USA bank covering the PURCHASE ORDER for the first delivery of STAGE 0 of this AGREEMENT, in the form of the request attached hereto as Appendix VI, (b) within thirty (30) days of the execution and delivery of this AGREEMENT, FIOCRUZ shall provide to PROTALIX a fully executed and effective irrevocable letter of credit confirmed by a first class USA bank covering the PURCHASE ORDER for the first delivery of STAGE 0 of this AGREEMENT, in a form reasonably acceptable to PROTALIX, and (c) on or prior to submission of each subsequent PURCHASE ORDER [***] FIOCRUZ shall execute and deliver other irrevocable letters of credit confirmed by a first class USA bank covering the PURCHASE ORDER for such delivery under the AGREEMENT (in the same form as the letter of credit provided by FIOCRUZ for the first delivery of STAGE 0 of this AGREEMENT), together covering the total amount of the AGREEMENT, along the duration of the AGREEMENT. [***] Notwithstanding anything to the contrary herein, PROTALIX shall have no obligation to ship any PRODUCT for any year of this AGREEMENT until a fully executed and effective letter of credit for such PURCHASE ORDER of the AGREEMENT (that complies with the terms of this Section 6.5.1) is delivered to PROTALIX.

6.5.2 In the event that COMPLETION of the TECHNOLOGY TRANSFER is not achieved prior to the date occurring seven (7) years following the EFFECTIVE DATE, this AGREEMENT may be renewed, pursuant to and in accordance with Section 12.1; provided that, for each such renewal period, PURCHASE ORDERS and a letter of credit equivalent to those provided for in Section 6.5.1 are executed by FIOCRUZ and delivered to PROTALIX prior to such renewal

[***] Redacted pursuant to confidential treatment request.

ARTICLE 7. MANUFACTURE; COMMERCIALIZATION AND QUALITY CONTROL

7.1 Manufacture

7.1.1 During the TERM following the EFFECTIVE DATE, FIOCRUZ shall perform the applicable MANUFACTURING steps with respect to the PRODUCTS solely in the FACILITY and solely from the SUPPLIED MATERIALS supplied by PROTALIX to FIOCRUZ.

7.1.2 FIOCRUZ shall employ only the MANUFACTURING and other processes, and shall comply with the quality control standards, included in the PROTALIX TECHNOLOGY provided to FIOCRUZ and shall ensure that the PRODUCTS complies with the SPECIFICATIONS, GMP standards and all applicable Brazilian LAWS. There shall be no changes made to such processes, standards, or SPECIFICATIONS without PROTALIX's prior written consent.

7.1.3 FIOCRUZ represents and warrants that the FACILITIES and FIOCRUZ's MANUFACTURING practices at the FACILITIES shall at all times comply with all applicable Brazilian LAWS, SPECIFICATIONS and GMP standards.

7.1.4 FIOCRUZ shall use the PROTALIX TECHNOLOGY and SPECIFICATIONS (including any items provided pursuant to the TECHNOLOGY TRANSFER, such as the bioreactors, growth media, and cell banks) solely for the purposes of MANUFACTURING the PRODUCTS in the FACILITY, pursuant to and in accordance with this AGREEMENT, and not in connection with any other pharmaceutical products unless agreed to by the PARTIES in writing in advance.

7.1.5 PROTALIX may, in its sole discretion, modify the SPECIFICATIONS upon written notice to FIOCRUZ. PROTALIX shall use commercially reasonable efforts to provide written justification of such changes (which shall include information and data supporting such change) to FIOCRUZ in a reasonably prompt manner so that FIOCRUZ may update the PRODUCT registration in ANVISA held by FIOCRUZ.

7.2 Commercialization

7.2.1 FIOCRUZ shall use its best efforts to diligently COMMERCIALIZE the PRODUCTS in accordance with this AGREEMENT.

7.2.2 FIOCRUZ represents and warrants that FIOCRUZ's COMMERCIALIZATION shall at all times comply with all applicable Brazilian LAWS and the highest commercial and ethical standards.

7.2.3 FIOCRUZ's COMMERCIALIZATION, including with respect to the marketing and promotion, of the PRODUCTS shall only be for the approved indications, dosage forms and strengths included in the FIELD.

7.3 Access to the Facilities and Technical Visits; Payment for Technical Assistance.

7.3.1 During the TECHNOLOGY TRANSFER, PROTALIX shall have the right to enter the FACILITIES, during normal business hours to check and verify the FACILITY, DRUG SUBSTANCES, PRODUCTS, SUPPLIED MATERIALS and any MANUFACTURING processes, quality control standards and other activities relating to the foregoing or this AGREEMENT that are performed at the FACILITY to ensure compliance with this AGREEMENT (including compliance with the SPECIFICATIONS, GMP standards, and applicable Brazilian LAW and achievement of COMPLETION REQUIREMENTS). FIOCRUZ shall implement any mitigation plan reasonably identified by PROTALIX to address any such findings.

7.3.2 FIOCRUZ shall allow PROTALIX and/or its representatives/designees reasonable access to the FACILITIES and to its records in order to enable PROTALIX to conduct periodic reviews during

normal business hours of the health and safety practices and performance of the FACILITIES. In connection with such audit or evaluation, FIOCRUZ shall cooperate in the completion of a Health & Safety survey by PROTALIX or in the scheduling of a Health & Safety audit of any FACILITY, as applicable. FIOCRUZ shall correct, at its own cost and expense, any material deficiencies in its health and safety management practices that are identified to it. FIOCRUZ acknowledges that such reviews and evaluations conducted by PROTALIX are for the benefit of PROTALIX only and are not a substitute for FIOCRUZ's own health and safety management obligations under this AGREEMENT and, accordingly, FIOCRUZ may not rely upon them.

7.4 Quality Control Testing/Validation.

7.4.1 For each STAGE of the TECHNOLOGY TRANSFER, FIOCRUZ shall be responsible for validation of the MANUFACTURING and operating processes and quality control testing as conducted by FIOCRUZ at the FACILITIES. During the TECHNOLOGY TRANSFER, upon PROTALIX's request, FIOCRUZ shall, at FIOCRUZ's sole cost and expense, (a) submit a sample of any production batch of the PRODUCTS for parallel quality control testing to be performed by PROTALIX or representatives/designees, (b) make available to PROTALIX any books and records relating to the MANUFACTURING and operating processes, quality control testing, DRUG SUBSTANCE, SUPPLIED MATERIALS and the PRODUCTS, and (c) provide to PROTALIX all documentation reasonably necessary to evidence that the PROTALIX TECHNOLOGY and SUPPLIED MATERIALS have been used only in accordance with this AGREEMENT.

7.4.2 During the TERM of the AGREEMENT, in accordance with Section 7.4.1(a), FIOCRUZ will supply with each sample supplied to PROTALIX, a certificate of analysis duly signed by an individual qualified and authorized with respect to the PRODUCTS in sufficient detail to demonstrate conformity with the SPECIFICATIONS. If any delivery consists of the PRODUCTS of more than one production batch, FIOCRUZ shall provide a certificate of analysis for each such batch.

7.4.3 In the event that the results of the quality control tests of PROTALIX and FIOCRUZ are not consistent, FIOCRUZ shall, and PROTALIX, shall have the right but not the obligation to, repeat such tests, at FIOCRUZ's sole cost and expense. In the event PROTALIX and FIOCRUZ repeated such tests and such inconsistency remains, an independent laboratory having a confirmed experience in *Recombinant Enzyme* testing agreed upon by both PROTALIX and FIOCRUZ in good faith shall be requested to perform the test and such test shall determine whether a batch can be released or not. The costs of such test by the laboratory shall be borne by FIOCRUZ. Any batch that has been finally rejected shall be destroyed at FIOCRUZ' expense and FIOCRUZ shall provide PROTALIX with destruction certificates. In case FIOCRUZ experiences, during the TECHNOLOGY TRANSFER, problems in meeting the quality of SPECIFICATIONS of PRODUCTS, the PARTIES will define corrective measures to ensure quality and carry out validation of such measures.

7.4.4 FIOCRUZ shall be responsible for and reimburse PROTALIX for costs and reasonably agreed upon expenses incurred to provide technical assistance or training to FIOCRUZ, including all costs and expenses relating to travel (business class tickets for all flights), local transportation, hotel, food, and reasonable per diem expenses.

7.4.5 In accordance with the payment terms in Article 9, FIOCRUZ shall pay PROTALIX for the technical assistance and training provided by PROTALIX to FIOCRUZ (as agreed upon by PROTALIX and FIOCRUZ), at the following rates:

Employee (other than Supervisors, Managers or Directors)	[***] U.S. dollars per hour
Supervisor:	[***] U.S. dollars per hour
Manager:	[***] U.S. dollars per hour
Senior Manager or Director	[***] U.S. dollars per hour

ARTICLE 8. USE OF NAMES AND MARKS; PATENT RIGHTS

8.1 Product Mark License to FIOCRUZ. PROTALIX hereby grants to FIOCRUZ, during the Term, a non-exclusive, non-transferable, non-sublicensable, limited license to use the Product Marks as they exist on the labeling and packaging of the FINISHED PACKAGED Product at the time such FINISHED PACKAGED PRODUCT is supplied to FIOCRUZ by PROTALIX hereunder in connection with COMMERCIALIZATION of such PRODUCT within the Territory for the Field in accordance with the terms and conditions of this AGREEMENT. For the avoidance of doubt, FIOCRUZ is not granted any rights to display the PRODUCT MARKS other than on the labeling and packaging of such FINISHED PACKAGED PRODUCT as such PRODUCT MARKS are already displayed thereon.

[***] Redacted pursuant to confidential treatment request.

8.2 Quality Control.

8.2.1 FIOCRUZ shall not alter, remove, cover or otherwise modify the labeling or packaging of any FINISHED PACKAGED PRODUCT (or any PRODUCT MARK thereon). The quality of the FINISHED PACKAGED PRODUCT sold or otherwise distributed by FIOCRUZ must be of the same quality as the FINISHED PACKAGED PRODUCT at the time it was supplied to FIOCRUZ hereunder.

8.2.2 FIOCRUZ shall (a) comply with all applicable Brazilian Laws pertaining to the proper use and designation of the Product Marks, (b) modify the labeling and packaging of any FINISHED PACKAGED PRODUCT as directed by PROTALIX, (c) not use any Product Mark as a corporate name, business name, or trade name, (d) not use the PRODUCT MARKS in connection with any SUPPLIED MATERIALS or PRODUCTS other than the FINISHED PACKAGED PRODUCT or in any manner not expressly permitted hereunder, and (e) not use any Product Mark in a manner that would reasonably be expected to materially impair the validity, reputation, or distinctiveness of any Product Mark.

8.3 Prosecution and Maintenance of Product Marks. PROTALIX (or its licensors) shall have the sole right, but not the obligation, through counsel of its choosing, to prosecute and maintain the Product Marks in and outside the Territory.

8.4 Enforcement of Product Marks. FIOCRUZ shall promptly notify PROTALIX in the event of any actual, potential or suspected infringement of a Product Mark by any Third PARTY. [***] shall have the sole right, but not the obligation, to institute litigation or take other remedial measures in connection with Third PARTY infringement of Product Marks. [***] shall be solely entitled to any and all recoveries from THIRD PARTIES resulting from such litigation or other appropriate action, after reimbursement from such recoveries of [***] costs and expenses in enforcing the PRODUCT MARKS in such litigation or other action [***].

8.5 Use of Names.

8.5.1 No right, expressed or implied, is granted by this AGREEMENT to FIOCRUZ to use in any manner the name or any other trade name of PROTALIX or its Affiliates.

8.5.2 Notwithstanding the foregoing Article 8.5.1, FIOCRUZ shall have the right to use the PROTALIX corporate name, subject to PROTALIX's trademark usage guidelines provided to FIOCRUZ from time to time, on package inserts, packaging or trade packaging associated with the Products in the Territory solely to the extent required by applicable Laws. FIOCRUZ will submit for PROTALIX's prior written approval a sample of each such proposed use of the PROTALIX corporate name prior to any use thereof.

8.6 FIOCRUZ Covenants.

8.6.1 Other than as expressly permitted in this Article 8, FIOCRUZ shall not (a) use, register, or apply to register any name, mark, domain name, or logo that consists of or is confusingly similar to any name, mark, domain name, or logo owned or controlled by PROTALIX or its AFFILIATES; (b) use any name, mark, domain name, or logo owned or controlled by PROTALIX or its AFFILIATES together with any other mark or name, without prior written consent from such PARTY; or (c) take any action whereby any name, mark, domain name, or logo owned or controlled by PROTALIX or its AFFILIATES becomes invalid, unenforceable, generic or otherwise impaired.

8.6.2 FIOCRUZ shall not take any action that in any way might tend to disparage, diminish, or reflect negatively upon the goodwill, reputation or value of PROTALIX, the PRODUCT, FIOCRUZ or any name, mark domain name or logo owned or controlled by PROTALIX or its AFFILIATES

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8.7 Prosecution and Maintenance of PROTALIX PATENT RIGHTS. PROTALIX shall have the sole right, but not the obligation, through counsel of its choosing, to prosecute and maintain the PROTALIX PATENT RIGHTS in and outside the TERRITORY.

[***] Redacted pursuant to confidential treatment request.

8.8 Enforcement of PROTALIX PATENT RIGHTS. FIOCRUZ shall promptly notify PROTALIX in the event of any actual, potential or suspected infringement of a PROTALIX PATENT RIGHT by any Third PARTY. PROTALIX shall have the sole right, but not the obligation, to institute litigation or take other remedial measures in connection with Third PARTY infringement of PROTALIX PATENT RIGHTS. FIOCRUZ shall [***] cooperate with PROTALIX in any such litigation or other remedial measure, including by being named as a party if necessary to institute or maintain such litigation or other remedial measure. If FIOCRUZ is so named, it may hire its own counsel at its sole cost and expense to participate in such litigation or other remedial measure, provided that PROTALIX and its counsel shall at all times and in all cases control such litigation or other remedial measure. [***][***] shall be entitled to any and all recoveries from THIRD PARTIES resulting from such litigation or other remedial action, after reimbursement from such amount of [***] costs and expenses in enforcing the PROTALIX PATENT RIGHTS in such litigation or action [***].

ARTICLE 9. ROYALTY, REPORTING AND PAYMENT TERMS

9.1 Royalties. Commencing upon FIOCRUZ's completion of a Phase III clinical trial and obtaining a GOVERNMENTAL APPROVAL from ANVISA for the MANUFACTURE entirely by FIOCRUZ of the FINAL PRODUCT in the TERRITORY, FIOCRUZ shall pay to PROTALIX for the exploitation of the PROTALIX patent RIGHTs and the PROTALIX TECHNOLOGY in the TERRITORY a running royalty of [***] of Net Sales (the "ROYALTY PAYMENTS"), on a quarterly basis in the manner described in this Article 9. For the avoidance of doubt, (i) FIOCRUZ shall not COMMERCIALIZE the FINAL PRODUCT until completion of a Phase III clinical trial and obtaining a GOVERNMENTAL APPROVAL from ANVISA for the MANUFACTURE entirely by FIOCRUZ of the FINAL PRODUCT in the TERRITORY, and (ii) the requirement to pay ROYALTY PAYMENTS shall survive any termination or expiration of this AGREEMENT until the expiration of the last to expire PROTALIX patent in Brazil.

9.2 Royalty Reporting and Payment. Not later than thirty (30) days after the end of each calendar quarter during the Term (a "REPORTING PERIOD"), FIOCRUZ shall (a) submit to PROTALIX a written report setting forth in reasonable detail (i) gross sales of FINAL Product during the Reporting Period, (ii) Net Sales and number of units of FINAL Product sold or distributed during the Reporting Period, as well as the computation of such Net Sales amounts, (iii) inventory of FINAL PRODUCT at the beginning and end of such Reporting Period, and (iv) all other information related to the business of FIOCRUZ during such Reporting Period to the extent necessary to enable the calculation of amounts payable hereunder to be verified, and (b) pay PROTALIX all amounts due for such Reporting Period.

9.3 Other Payments. Other than the Royalty Payments, which are subject to Article 9.2, all other payments (including any reimbursements) arising hereunder shall, unless otherwise set forth herein, be paid not later than [***] of receipt of an invoice or notice therefor.

9.4 Interest and other Charges. In the event that PROTALIX does not receive on or prior to the date when due hereunder all amounts owed by FIOCRUZ to PROTALIX, such unpaid amount shall be automatically subject to a flat penalty of [***] and monthly adjustment for inflation based on the positive variation of the [IGP-M/FGV] in the period. Any such amount (as increased by the penalty and the monetary correction mentioned above) shall bear default interest from the due date until payment is received by such PARTY at a rate of [***] per month (the "RATE"). The above additional charges shall be in addition to, and not in lieu of, any other remedy available to PROTALIX hereunder.

9.5 Taxes and Other Charges. FIOCRUZ represents and warrants to PROTALIX that, as of the EXECUTION DATE, there are no Brazilian taxes, customs, duties, assessments, excises, registration fees, surtax, stamp duties, or any other charges that are required to be levied upon or withheld from the importation of or assessed against the material furnished or rights licensed by PROTALIX hereunder, or for or on account of the operation of the FACILITY, the purchase, MANUFACTURE, COMMERCIALIZATION by or on behalf of FIOCRUZ of the SUPPLIED MATERIALS and PRODUCTS, or other business of FIOCRUZ contemplated under this AGREEMENT, including any withholding taxes or any such payments related to the registration or recording of this AGREEMENT, or any related documents (not including any ANVISA registration fees) (collectively "TAXES AND FEES"), other than as set forth in Exhibit C (which shall include details regarding applicable percentages and amounts if any such TAXES AND FEES, and the PARTY to be responsible therefore). If there are any TAXES AND FEES under Brazilian LAW that are not set forth on Exhibit C and are, or during the TERM become, in effect (whether as a result of any change in, or amendment to, Brazilian LAWS or otherwise), and such TAXES AND FEES materially change the dollar amount or timing of payments expected to be received by PROTALIX hereunder, then (i) the PARTIES shall discuss in good faith how to address such change in a mutually acceptable manner to compensate PROTALIX for such change (e.g., by an increase in pricing of PRODUCT, an increase in amount of PRODUCT to be purchased, etc.), and (ii) if the PARTIES do not come to an agreement in writing with respect thereto within thirty (30) calendar days, PROTALIX shall have the right to terminate this AGREEMENT immediately upon written notice to FIOCRUZ.

[***] Redacted pursuant to confidential treatment request.

9.6 Currency and Mode of Payment. All payments to be made hereunder by one PARTY to another PARTY shall be paid in United States dollars, by electronic transfer in immediately available funds via either a bank wire transfer, an electronic funds transfer mechanism, at the paying PARTY's election, to the bank account designated in Appendix VII or otherwise designated by the PARTY entitled to receive such payment. ROYALTY PAYMENTS and other payments due hereunder shall be converted into U.S. dollars at the exchange rate quoted by Brazilian Central Bank (or its successor in interest) at its market rate for the purchase of U.S. dollars with the applicable currency that needs to be converted (e.g., the currency of the Net Sales received) and applied by that bank on the day such payment is made.

9.7 Permits. FIOCRUZ assumes the sole responsibility of procuring Permits for the export of funds as may be required in the Territory; provided, however, that to the extent that it is impossible to make such payments due to the "blocking" of funds by LAW, such "blocked" funds shall be deposited to the credit of PROTALIX, in such depository as PROTALIX designates or, at the option of PROTALIX, paid directly to a Brazilian entity designated by PROTALIX. Other than as set forth on Exhibit C, there shall be no deduction or offset from, nor shall FIOCRUZ have any right to hold back any payment of, any payments owed by FIOCRUZ hereunder for any reason, including for any uncollectible accounts or other TAXES AND FEES for which FIOCRUZ is responsible hereunder, or for any banking cost or cost of exchange or expense of transmitting said funds. FIOCRUZ shall not conduct its business in any manner intended to reduce the ROYALTY PAYMENTS required to be paid by FIOCRUZ hereunder.

ARTICLE 10. OWNERSHIP OF ENHANCEMENTS

10.1 Any invention made, conceived or reduced to practice by PROTALIX in connection with the performance of the obligations of this AGREEMENT relating to: (i) a pharmaceutical product with the same chemical composition as the PRODUCT or (ii) an IMPROVEMENT to the PRODUCT or (iii) an IMPROVEMENT to the process or specifications provided by PROTALIX to FIOCRUZ, shall be the exclusive property of PROTALIX. PROTALIX, in its sole discretion, may file for patent protection in its own name for any such invention. PROTALIX shall, and hereby does, grant to FIOCRUZ a non-exclusive, irrevocable, perpetual, worldwide, royalty-free license to use, sublicense, practice and otherwise exploit in any manner any such invention and any patent or other intellectual property or proprietary rights therein throughout the world.

ARTICLE 11. CONFIDENTIALITY

11.1 All non-public information, which is received or made available by or on behalf of PROTALIX or FIOCRUZ (each, in such capacity, the "RECIPIENT") from or on behalf of the other (in such capacity, the "DISCLOSING PARTY") prior to or during the Term of this AGREEMENT in connection with this AGREEMENT or relating hereto, including without limitation, relating to the PRODUCT or any other pharmaceutical product that contains DRUG SUBSTANCE ("CONFIDENTIAL INFORMATION") shall be maintained in confidence and shall not be disclosed to any Third PARTY nor used for purposes other than as set forth herein, without the prior written consent of the DISCLOSING PARTY, except to the extent that the CONFIDENTIAL INFORMATION: (a) is known to the RECIPIENT prior to disclosure by the DISCLOSING PARTY to the RECIPIENT through no wrongful act of the RECIPIENT, provided that the RECIPIENT is able to provide competent proof of such prior knowledge; (b) is obtained by the RECIPIENT in a lawful manner from a source other than the DISCLOSING PARTY, which source (i) was not required to hold such secrets or information in confidence, and (ii) was not limited or restricted in its disclosure thereof, (c) has become public knowledge other than through the fault of the RECIPIENT; (d) has been developed by the RECIPIENT independently of the information received as established by written records. The PROTALIX TECHNOLOGY, SPECIFICATIONS and all other information relating thereto or to the business, operations, research or development of PROTALIX, shall be deemed included in the CONFIDENTIAL INFORMATION of PROTALIX.

11.2 Notwithstanding the foregoing, RECIPIENT shall be entitled to disclose CONFIDENTIAL INFORMATION to the extent disclosure by the RECIPIENT is required: (a) to submit applications by the RECIPIENT for GOVERNMENTAL APPROVALS (i) in the case of FIOCRUZ as RECIPIENT, to MANUFACTURE and COMMERCIALIZE the Product in accordance with the terms and conditions of this AGREEMENT, or (ii) in the case of PROTALIX as the RECIPIENT, in relation to the COMPOUND, DRUG SUBSTANCE, or PRODUCT, (b) in the case of PROTALIX as the RECIPIENT, in connection with filing or prosecution of the PROTALIX PATENT RIGHTS or the PRODUCT MARKS, prosecuting or defending litigation relating thereto or to the PROTALIX TECHNOLOGY, or (c) by LAW or by any THIRD PARTY LICENSE; provided that the RECIPIENT shall use commercially reasonable efforts to obtain confidential treatment of any CONFIDENTIAL INFORMATION to the extent applicable and, if reasonably practicable under the circumstances, provide the DISCLOSING PARTY with sufficient advance notice of such intended disclosure so that the DISCLOSING PARTY will have the opportunity to seek, at its own cost, an appropriate protective order or other remedy, to the extent applicable, or waive compliance with the provisions of this AGREEMENT. If the DISCLOSING

PARTY seeks a protective order, the RECIPIENT will cooperate. If the DISCLOSING PARTY fails to obtain a protective order or waive compliance with the relevant portions of this AGREEMENT, the RECIPIENT will disclose only that portion of information concerning the COMPOUND or PRODUCT which its legal counsel determines it is required to disclose.

11.3 For the avoidance of doubt, the [***] shall be deemed included in the CONFIDENTIAL INFORMATION of PROTALIX. In addition to the obligations set forth in Article 11.1 and 11.2, FIOCRUZ agrees to (i) treat the [***] with the utmost confidence and in a manner at least as protective as the manner in which FIOCRUZ protects its own most highly sensitive confidential information, trade secrets and know-how, (ii) not use such [***] for any purpose other than for the MANUFACTURING of the FINAL PRODUCT, and (iii) not disclose the information to any PERSON, other than as permitted pursuant to Article 11.2 to PERSONS (a) who have a need to know such information for the purpose of MANUFACTURING the FINAL PRODUCT, (b) who are informed by FIOCRUZ of the confidential nature thereof and the obligations under this AGREEMENT with respect thereto, and (c) who agree in writing with PROTALIX to comply with the obligations of FIOCRUZ under this Article 11 with respect thereto.

11.4 The confidentiality obligations set forth in this Article 11 shall survive the termination or expiration of this AGREEMENT until fifteen (15) years from the EFFECTIVE DATE. Notwithstanding anything to the contrary herein, FIOCRUZ's obligations under this Article 11 with respect to the [***] shall survive the termination or expiration of this AGREEMENT for no less than fifteen (15) years from the completion of the transfer of such [***] to FIOCRUZ.

ARTICLE 12. TERM AND TERMINATION

12.1 This AGREEMENT shall come into force and effect as of the EFFECTIVE DATE, and shall remain in force for seven (7) years following the EFFECTIVE DATE, and may be renewed upon the written agreement of FIOCRUZ and PROTALIX, if INPI authorizes such renewal, for additional five (5) years periods. If in the end of the initial seven (7) year period or any such renewal period the TECHNOLOGY TRANSFER has not been COMPLETED, the PARTIES may renew the AGREEMENT for the period needed for the COMPLETION of the TECHNOLOGY TRANSFER in accordance with the foregoing sentence (the initial period and any such renewal periods, collectively, "TERM 1"), and upon COMPLETION of the TECHNOLOGY TRANSFER TERM 1 shall immediately and automatically expire and TERM 2 shall immediately and automatically commence.

12.2 FIOCRUZ shall pay royalties hereunder to PROTALIX for the PROTALIX PATENT RIGHTS for the period of time beginning on the completion of TERM 1 until the later of expiration of the last to expire PROTALIX patent in Brazil in accordance with ARTICLE 9 ("TERM 2"). The TERM 2 is valid only for the purpose of royalties payment, any terms and conditions relating to PROTALIX PATENT RIGHTS or PRODUCT MARKS in any way (including, for the avoidance of doubt, all license rights and restrictions), and any other obligations that survive termination or expiration of this AGREEMENT. The other obligations of this AGREEMENT (i.e., those obligations not referenced in the foregoing sentence) shall expire with the end of TERM 1.

12.3 Without limiting any other provision of this AGREEMENT, this AGREEMENT may be terminated by PROTALIX as follows:

(a) if FIOCRUZ materially breaches its representations or warranties made in this AGREEMENT, or materially breaches or materially defaults in the performance or observance of any of its obligations under this AGREEMENT, and such breach or default is not cured within [***] after the giving of written notice by PROTALIX, specifying such breach or default, then PROTALIX shall have the right to terminate this AGREEMENT by providing FIOCRUZ written notice following the expiration of such [***][***] period (such termination to be effective upon receipt of such termination notice);

(b) immediately upon written notice to FIOCRUZ if any GOVERNMENTAL AUTHORITY announces plans to privatize FIOCRUZ and a competitor of PROTALIX acquires FIOCRUZ or any part of FIOCRUZ that is responsible for the MANUFACTURE or COMMERCIALIZATION of PRODUCTS;

(c) if FIOCRUZ fails to make any payment when due in accordance with the terms and conditions of this AGREEMENT and such failure to pay is not cured within [***] after the giving of written notice by PROTALIX of such failure, then PROTALIX shall have the right to terminate this AGREEMENT by providing FIOCRUZ written notice following the expiration of such [***] period (such termination to be effective upon receipt of such termination notice);

(d) immediately upon written notice if FIOCRUZ undergoes a change of control (as such term is defined in the definition of AFFILIATE);

(e) immediately upon written notice if FIOCRUZ orders, purchases, accepts or otherwise imports from a third party any product that is a therapy for the treatment of Gaucher Disease;

[***] Redacted pursuant to confidential treatment request.

(f) immediately upon written notice in the event of: (i) FIOCRUZ's insolvency or bankruptcy, (ii) a liquidation committee or team being formed pursuant to the liquidation rules or Laws of any applicable jurisdiction with respect to FIOCRUZ, or substantially all of the property or assets of FIOCRUZ is under custody by the liquidation committee under the provisions of any bankruptcy, insolvency, or similar LAW, (iv) FIOCRUZ making an assignment for the benefit of its creditors, or (v) FIOCRUZ being dissolved; and

(g) The purchase by and supply to FIOCRUZ of SUPPLIED MATERIALS during each STAGE in order to proceed to the subsequent STAGE of TECHNOLOGY TRANSFER shall occur subject to [***] and PROTALIX's prior written approval of such quantities. In the event that (i) PROTALIX does not agree in advance in writing with such quantities proposed by the Brazilian MOH or (ii) the [***] and corresponding PURCHASE ORDERS issued by FIOCRUZ to PROTALIX for any year are less than the amount set forth in the following chart for any given year, PROTALIX shall have the right to terminate this AGREEMENT immediately upon providing FIOCRUZ written notice:

Yearly Termination Threshold

Year	**Termination Threshold**
From January 1, 2014 until July 31, 2015	[***]
From August1, 2015 until July 31, 2016	[***]
From August 1, 2016 until July 31, 2017	[***]
From August 1, 2017 until July 31, 2018	[***]
From August 1, 2018 until July 31, 2019	[***]
From August 1, 2019 until July 31, 2020	[***]

12.4 Without limiting any other provision of this AGREEMENT, this AGREEMENT may be terminated by FIOCRUZ as follows:

(a) if PROTALIX materially breaches its representations or warranties made in this AGREEMENT, or materially breaches or defaults in the performance or observance of any of its respective obligations under, this AGREEMENT, and such breach or default is not cured within [***] after the giving of written notice by FIOCRUZ to PROTALIX specifying such breach or default, then FIOCRUZ shall have the right to terminate this AGREEMENT by providing PROTALIX written notice following the expiration of such [***] period (such termination to be effective upon receipt of such termination notice);

(b) immediately upon notice to PROTALIX if FIOCRUZ due to any change in Brazilian LAW is unable to maintain compliance with this AGREEMENT; provided FIOCRUZ used its best efforts to prevent any of the foregoing events from occurring and to mitigate or cure any effects thereof prior to exercising such termination right; and

(c) if the pharmaceutical product *plant cell expressed recombinant Glucocerebrosidase* in a finished dosage form of a drug product that contains DRUG SUBSTANCE (excluding any ORAL FORMULATION) is recalled by both ANVISA and the United States Food and Drug Administration in a manner that is not curable within [***]. In the case of termination pursuant to this Section 12.4(c), FIOCRUZ shall not be required to pay any outstanding payment obligations incurred prior to the effective date of such termination under this AGREEMENT for any PRODUCT batches subject to such recall.

12.5 FIOCRUZ shall notify PROTALIX at least twenty (20) days prior to the occurrence of any of the events or scenarios described in Articles 12.3(b) and (d) and 12.4(b), or, if not possible on such time frame, as soon as possible prior to such occurrence.

12.6 Termination of this AGREEMENT shall be in addition to, and not in lieu of, any other rights or remedies available to the terminating PARTY under this AGREEMENT or applicable Brazilian LAW. Termination of this AGREEMENT in accordance with the terms hereof shall not be the basis for any compensation or other claim for damages resulting therefrom (including any lost profits due to such termination), other than as set forth in Section 12.7.

12.7 Termination of this AGREEMENT for any reason (a) shall be without prejudice to and shall not impair or limit in any manner PROTALIX's right to receive payment from FIOCRUZ in respect of any payment obligations incurred prior to the effective date of such termination, whether or not the due date for such payment is after such effective date of termination and (b) shall not release a PARTY hereto from any indebtedness, liability, payment or other obligation incurred hereunder (including liability for breach of this AGREEMENT) by such PARTY prior to the effective date of such termination.

[***] Redacted pursuant to confidential treatment request.

ARTICLE 13. EFFECTS OF TERMINATION

13.1 Except as expressly provided for hereunder, upon the effective date of termination of this AGREEMENT in accordance with this AGREEMENT, all licenses and rights granted to FIOCRUZ herein shall automatically and immediately terminate and FIOCRUZ shall immediately cease all use of the PROTALIX TECHNOLOGY, PROTALIX PATENTS, SPECIFICATIONS and any other CONFIDENTIAL INFORMATION provided to FIOCRUZ hereunder.

13.2 FIOCRUZ shall, promptly after termination of this AGREEMENT, provide to PROTALIX or its designee (or upon PROTALIX's direction with respect to specific items, destroy) all documents, data, reports, records, regulatory correspondence and other materials and information (and any copies thereof) that contain or are related to the PROTALIX TECHNOLOGY, CONFIDENTIAL INFORMATION disclosed by PROTALIX, and the COMPOUNDS, DRUG SUBSTANCES, CELL BANK, reagents, and PRODUCTS (including and GOVERNMENTAL APPROVALS and regulatory filings with respect thereto) in a form and format useable by PROTALIX. Upon such termination, FIOCRUZ shall assign and transfer to PROTALIX or its designee all of FIOCRUZ's right, title and interest in and to all GOVERNMENTAL APPROVALS for or related to the PRODUCTS, COMPOUND or DRUG SUBSTANCE in the Territory and any related data and other materials transferred or delivered or deliverable by FIOCRUZ pursuant to this Article 13.2. FIOCRUZ shall execute and deliver to PROTALIX such documents, and take such other actions requested by PROTALIX that are necessary or appropriate to carry out the intent and purposes of this Article 13.2 and to perfect and confirm such assignment, including submitting letters to the GOVERNMENTAL AUTHORITIES in forms reasonably acceptable to PROTALIX.

13.3 Following termination of this AGREEMENT, upon a PARTY's reasonable request and at such requesting PARTY's cost, the other PARTY shall reasonably cooperate with the requesting PARTY (including by providing relevant information and data) in connection with any requests or investigations of a regulatory authority, any Third PARTY claims against the requesting PARTY, or such requesting PARTY's efforts to comply with Laws, relating to the PRODUCTS, COMPOUND, DRUG SUBSTANCE, PROTALIX TECHNOLOGY, or SPECIFICATIONS.

13.4 Upon termination of this AGREEMENT, FIOCRUZ shall terminate the MANUFACTURE and COMMERCIALIZATION of any COMPOUND, DRUG SUBSTANCE, or PRODUCTS and, at PROTALIX's sole option, shall (a) only in the event of termination by PROTALIX pursuant to Article 12.3, arrange the sale to PROTALIX or its designee at FIOCRUZ's cost of all (or at PROTALIX's option, a portion of the) SUPPLIED MATERIAL, DRUG SUBSTANCES and PRODUCTS in FIOCRUZ's inventory, and/or (b) dispose of all (or at PROTALIX's option, a portion of the) SUPPLIED MATERIAL, DRUG SUBSTANCES and PRODUCTS in FIOCRUZ's inventory.

13.5 Upon termination of this AGREEMENT, FIOCRUZ shall cooperate with PROTALIX to effect a cancellation or termination of any recordation of this AGREEMENT with the appropriate Governmental Authorities in the Territory, and the FIOCRUZ will grant, and hereby does grant, to PROTALIX an irrevocable power of attorney coupled with an interest to effect such cancellation within twenty (20) days after the termination of this AGREEMENT.

ARTICLE 14. BOOKS AND RECORDS

14.1 FIOCRUZ shall keep and maintain during the TERM and for one (1) years after the termination of this AGREEMENT, accurate and correct books and records setting forth gross sales of the PRODUCTS, Net Sales, number of units of PRODUCT sold, inventory of PRODUCT and all other information related to the business of FIOCRUZ necessary to enable the calculation of amounts payable hereunder to be verified and the confirmation of FIOCRUZ's compliance with this AGREEMENT. PROTALIX shall have the right to request that an independent accountant reasonably selected by it examine FIOCRUZ's books and records at any reasonable time, upon reasonable notice and at the Facilities or other facilities where such books and records are normally kept. The opinion of such independent accountants regarding such payments shall be binding on the PARTIES, other than in the case of manifest error. Except as set forth below, the auditing PARTY shall bear the cost of any such examination and review.

14.2 If the review of FIOCRUZ's records reveals that FIOCRUZ failed to accurately report information pursuant to Article 9.2 or otherwise underpaid any amounts due hereunder, then FIOCRUZ's shall promptly pay PROTALIX the amount of any underpayment due hereunder, which shall be subject to all additional charges mentioned in Article 9.4 above, including the default interest at the Rate. If such discrepancy is greater than five percent (5%) of the amount due, FIOCRUZ shall promptly reimburse all costs incurred by PROTALIX in connection with such examination.

ARTICLE 15. GOVERNING LAW

15.1 The PARTIES agree that this AGREEMENT shall be governed by and construed in accordance with the laws of Brazil and the courts of Brazil shall have jurisdiction over any disputes arising in connection with this AGREEMENT. It is acknowledged that PROTALIX and FIOCRUZ shall not be excluded from adjudicating and enforcing their rights under this AGREEMENT as relate to countries other than Brazil (including but not limited to enforcing any restriction on a PARTY outside the TERRITORY) in courts other than the courts of Brazil.

ARTICLE 16. INDEMNIFICATION; DISCLAIMER; LIMITATION OF LIABILITY

16.1 FIOCRUZ shall indemnify, defend and hold PROTALIX and its AFFILIATES and their respective directors, officers, shareholders, representatives, agents, successors, assigns, licensors and employees harmless from and against all Losses, in each case to the extent arising out of (a) any acts or omissions of FIOCRUZ or any of its Affiliates, agents, consultants or contractors in connection with its activities under this AGREEMENT, including MANUFACTURE, use or sale of the SUPPLIED MATERIALS, COMPOUND, Drug Substance and/or Products, unless such Losses are for Losses to which FIOCRUZ is entitled to indemnification pursuant to Article 16.2, as applicable, (b) the breach of any covenant, warranty or representation made by FIOCRUZ under this AGREEMENT, or (c) the negligence, recklessness, or willful misconduct of, or violation of Brazilian LAW by, FIOCRUZ or any of its Affiliates, agents, consultants or contractors.

16.2 PROTALIX shall indemnify, defend and hold FIOCRUZ and its AFFILIATES and their respective directors, officers, shareholders, representatives, agents, successors, assigns, and employees harmless from and against all Losses arising from Third PARTY Claims that the MANUFACTURE and sale of the PRODUCTS by FIOCRUZ within the Territory for the Field in accordance with the terms and conditions hereof, infringes any Patent Rights of any THIRD PARTY.

16.3 For purposes of this AGREEMENT, “THIRD PARTY CLAIM” means a claim asserted by a Third PARTY (in no event to include any Affiliate of either PARTY) against a PARTY or any of its Affiliates, or any of their respective directors, officers, shareholders, representatives, agents, successors, assigns, licensors or employees. In the event a Third PARTY Claim is asserted or LOSSES are incurred with respect to any matter for which a PARTY or any of its Affiliates, or any of their respective directors, officers, shareholders, representatives, agents, successors, assigns, licensors and employees (the “INDEMNIFIED PARTY”) is entitled to indemnification hereunder, then the Indemnified PARTY shall promptly notify in writing the PARTY obligated to indemnify the Indemnified PARTY (the “INDEMNIFYING PARTY”) thereof; provided , however, that no delay on the part of the Indemnified PARTY in notifying the Indemnifying PARTY shall relieve the Indemnifying PARTY from any obligation hereunder unless (and then only to the extent that) the Indemnifying PARTY is prejudiced thereby.

16.4 The Indemnifying PARTY shall assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third PARTY Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying PARTY and reasonably acceptable to the Indemnified PARTY. The Indemnified PARTY shall have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third PARTY Claim that the Indemnifying PARTY is defending as provided in this AGREEMENT. Notwithstanding anything to the contrary contained herein, an Indemnified PARTY shall be entitled to assume the defense of any Third PARTY Claim with respect to the Indemnified PARTY, (i) upon written notice to the Indemnifying PARTY, in which case the Indemnifying PARTY shall be relieved of liability under Article 16.1 or 16.2, as applicable, solely for such Third PARTY Claim and related Losses, or (ii) in the event the INDEMNIFYING PARTY refuses or fails to assume the defense as required hereunder, in which case the Indemnifying PARTY shall not be relieved of liability under Article 16.1 or 16.2, as applicable, solely for such Third PARTY Claim and related Losses.

16.5 FIOCRUZ will not enter into any settlement of any THIRD PARTY CLAIM for which PROTALIX or any of its Affiliates, or any of their respective directors, officers, shareholders, representatives, agents, successors, assigns, licensors or employees is entitled to indemnification hereunder involving PROTALIX TECHNOLOGY, PROTALIX PATENT RIGHTS, CONFIDENTIAL INFORMATION of PROTALIX, PRODUCT MARKS, COMPOUND, Drug Substance, PRODUCTS or SUPPLIED MATERIALS, without such Indemnified PARTY’s prior written consent. Without limiting the foregoing, FIOCRUZ shall not, without the written consent of the Indemnified PARTY (which consent shall not be unreasonably withheld), effect any settlement of any pending or threatened litigation in which the Indemnified PARTY has sought indemnification hereunder by FIOCRUZ, unless such settlement involves solely monetary damages and includes an unconditional release of the Indemnified PARTY from all liability on claims that are the subject matter of such litigation.

16.6 IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE, SUFFERED BY PROTALIX, FIOCRUZ OR ANY OF THEIR RESPECTIVE AFFILIATES. THE FOREGOING SENTENCE SHALL NOT LIMIT (A) THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY AS PROVIDED HEREUNDER, (B) ANY LIABILITIES RESULTING FROM A BREACH OF THE CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 11 OR FROM USE OF ANY INTELLECTUAL PROPERTY OTHER THAN IN ACCORDANCE WITH THE LICENSE GRANTED PURSUANT TO ARTICLE 4, OR (C) ANY PAYMENT OBLIGATIONS UNDER THIS AGREEMENT. EXCEPT FOR LOSSES TO THE EXTENT RESULTING FROM PROTALIX'S GROSS NEGLIGENCE, FRAUD OR WILLFUL MISCONDUCT, IN NO EVENT SHALL PROTALIX'S TOTAL LIABILITY TO FIOCRUZ ARISING IN CONNECTION WITH THE SUPPLY OF SUPPLIED MATERIALS PURSUANT TO SECTION 6 HEREOF EXCEED, ON A SUPPLIED MATERIAL-BY-SUPPLIED MATERIAL BASIS, THE TOTAL AMOUNT PAID BY FIOCRUZ FOR SUCH SUPPLIED MATERIAL.

ARTICLE 17. WARRANTIES

17.1 Each PARTY hereby represents and warrants as of the EXECUTION DATE and the Effective Date that such PARTY has the requisite corporate power and authority to execute and deliver this AGREEMENT and to perform its obligations hereunder, and that the execution, delivery and performance of this AGREEMENT by such PARTY has been duly and validly authorized and approved by proper corporate action on the part of such PARTY, and such PARTY has taken all other action required by LAW, its certificate of incorporation, by-laws or other organizational documents, required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of the other PARTY, each PARTY represents and warrants as of the EFFECTIVE DATE that this AGREEMENT constitutes a legal, valid and binding obligation of such PARTY, enforceable against such PARTY in accordance with its terms.

17.2 FIOCRUZ hereby represents and warrants to PROTALIX as of the EXECUTION DATE and the EFFECTIVE DATE, and covenants to PROTALIX, as follows:

(a) In connection with the COMPOUND, Drug Substance and Products Manufactured by, or under authority of, FIOCRUZ: (i) any FACILITY and all equipment, tooling and molds utilized in the Manufacture hereunder by FIOCRUZ shall be maintained in good operating condition and shall be maintained and operated in accordance with all applicable Brazilian Laws and GMP, (ii) the Manufacturing, COMMERCIALIZATION and storage operations, procedures and processes utilized by FIOCRUZ hereunder (including any Facility) shall be in full compliance with all applicable Brazilian Laws, including GMP and Brazilian health and safety Laws, (iii) FIOCRUZ shall hold all Permits required by any Governmental Authority for it to Manufacture, COMMERCIALIZE and otherwise distribute the COMPOUND, Drug Substance and PRODUCTS in accordance with this AGREEMENT (subject to Article 5.1.5), and (iv) the PRODUCTS, or its containers, shall be marked by FIOCRUZ in accordance with the applicable patent marking LAWS.

(b) The COMPOUND, Drug Substance and Products, as applicable, shall be Manufactured, COMMERCIALIZED, packaged, labeled, handled, stored and shipped by FIOCRUZ, in accordance with the SPECIFICATIONS and in compliance with all applicable Brazilian Laws and GMP, and in accordance with the PHARMACOVIGILANCE AGREEMENT and any other quality assurance requirements provided in writing to FIOCRUZ by PROTALIX, and this AGREEMENT.

(c) FIOCRUZ shall not allow the introduction into the Drug SUBSTANCE or PRODUCTS of (i) any material that has not been used, handled or stored in accordance with the Specifications, all applicable Brazilian Laws, GMP, the PHARMACOVIGILANCE AGREEMENT, (ii) any material that would cause the Drug Substance or Products to be adulterated or misbranded within the meaning of any Brazilian Laws, and (iii) any defects in material and workmanship.

(d) Each PARTY does not, to such PARTY's knowledge, currently employ and will not knowingly employ during the Term, and does not, to such PARTY's knowledge, use as a subcontractor and will not knowingly use as a subcontractor during the Term, and such subcontractors do not, to such PARTY's knowledge, currently employ and will not employ or engage during the Term, any Person that has been debarred or has otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the ANVISA or any other Governmental Authority or professional body with respect to the performance of scientific or clinical investigations, or any Person finally convicted of a criminal offense, with no existing rights to appeal such conviction, in relation to: (i) the development or approval (including the process for development or

approval) of an abbreviated drug application, (ii) the development or approval of any drug product or otherwise relating to the regulation of any drug product, or (iii) bribery, payment of illegal gratuities, fraud, perjury, racketeering, blackmail, extortion, falsification or destruction of records or interference with, obstruction of an investigation into a prosecution of any criminal offense.

(e) FIOCRUZ shall operate and maintain all equipment used at the Facilities in a safe manner and provide adequate employee training with respect thereto.

(f) Each PARTY has not, to such PARTY's knowledge, and will not knowingly offer or pay, or authorize such offer or payment, of any money or anything of value or improperly seek to influence any Government Official in connection with this AGREEMENT. For purposes of this Article, a "GOVERNMENT OFFICIAL" is defined as and includes: (i) any elected or appointed government official (e.g., a member of a ministry of health); (ii) any employee or person acting for or on behalf of a government official, agency, or enterprise performing a governmental function; (iii) any political party, officer, employee, or person acting for or on behalf of a political party or candidate for public office; (iv) an employee or person acting for or on behalf of a public international organization; or (v) any person otherwise categorized as a Government Official under local law where "government" includes all levels and subdivisions of non-U.S. governments (i.e., local, regional, or national and administrative, legislative, or executive).

(g) FIOCRUZ shall (i) not use, sell or distribute the PRODUCTS or any other product that contains the DRUG SUBSTANCE, for any purpose other than as set forth herein, (ii) use the SUPPLIED MATERIALS and PROTALIX TECHNOLOGY solely for the purpose of converting such SUPPLIED MATERIALS into the PRODUCTS for sale within the Territory in the Field, in accordance with this AGREEMENT, (iii) not source materials for inclusion in the PRODUCTS other than through PROTALIX, and (iv) not sell, distribute or use a Product if it does not conform with the SPECIFICATIONS.

17.3 PROTALIX hereby represents and warrants to FIOCRUZ that, to its knowledge, as of the EXECUTION DATE and the Effective Date:

(a) The COMPOUND, DRUG SUBSTANCE, BULK PRODUCT, NAKED VIAL, CELL BANK and the FINISHED PACKAGED PRODUCT supplied by PROTALIX to FIOCRUZ hereunder is in full compliance with all applicable Brazilian Laws, including GMP and Brazilian health and safety Laws.

(b) The PROTALIX PATENT RIGHTS, PROTALIX TECHNOLOGY, PRODUCT MARKS or CONFIDENTIAL INFORMATION does not infringe any THIRD PARTY rights.

17.4 PROTALIX hereby covenants to FIOCRUZ that the COMPOUND, DRUG SUBSTANCE, BULK PRODUCT, NAKED VIAL, CELL BANK and the FINISHED PACKAGED PRODUCT supplied by PROTALIX to FIOCRUZ hereunder shall be in full compliance with GMP.

17.5 Disclaimer of Warranty. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND WITH RESPECT TO THE COMPOUND, DRUG SUBSTANCE, THE PRODUCT, PROTALIX PATENT RIGHTS, PROTALIX TECHNOLOGY, PRODUCT MARKS OR CONFIDENTIAL INFORMATION. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NON-INFRINGEMENT.

ARTICLE 18. PHARMACOVIGILANCE AGREEMENT/QUALITY AGREEMENT

18.1 The PARTIES agree to comply with the terms and conditions of the Pharmacovigilance Agreement set forth as Appendix VIII.

18.2 The PARTIES agree in good faith to establish mutually agreeable quality guidelines following the EXECUTION DATE and prior to distribution of PRODUCT by FIOCRUZ, which shall cover, amongst other matters, delivery and storage of PRODUCT by FIOCRUZ. The PARTIES agree to comply with such quality guidelines during the TERM.

ARTICLE 19. APPROVALS

19.1 Except where expressly stated otherwise herein, all approvals and consent rights of a PARTY under this AGREEMENT shall be in such PARTY's sole and absolute but good faith discretion. Any approval or consent may be subject to such conditions as such PARTY deems appropriate or be granted on a "test" or temporary basis, in each case to the extent identified to the PARTY requesting such approval or consent. If a PARTY does not grant any required approval or consent within ten (10) business Days of any submission or request for approval or consent, such submission or request shall be deemed to be disapproved.

ARTICLE 20. MISCELLANEOUS

20.1 Force Majeure. Neither PARTY shall be liable to the other PARTY for any losses or damages attributable to a default under or breach of this AGREEMENT that is the result of war (whether declared or undeclared), acts of God, revolution, acts of terror, fire, earthquake, flood, pestilence, riot, enactment or change of LAW (following the EXECUTION Date) making performance of this AGREEMENT by such PARTY impossible, accident(s), labor trouble, shortage of or inability to obtain material equipment or transport or any other cause beyond the reasonable control of such PARTY (each, a "FORCE MAJEURE EVENT"); provided that if such a cause occurs, then the PARTY affected will promptly notify the other PARTY of the nature and likely result and duration (if known) of such cause and use its commercially reasonable efforts to avoid or remove such causes of nonperformance as soon as is reasonably practicable. Upon termination of the Force Majeure Event, the performance of any suspended obligation or duty shall promptly recommence. If the event lasts for a period of longer than one (1) month, the PARTIES shall meet and work diligently to implement appropriate remedial measures. Notwithstanding anything to the contrary herein, despite the existence of any such Force Majeure Event affecting FIOCRUZ's ability to pay all monies due hereunder for PRODUCTS delivered or services or licenses provided hereunder, FIOCRUZ shall pay any such amounts immediately upon the termination of such FORCE MAJEURE EVENT without penalty for any such delay during the continuance of the FORCE MAJEURE EVENT, in accordance with the terms hereof.

20.2 Severability. If and solely to the extent that any provision of this AGREEMENT shall be invalid or unenforceable, such offending provision shall be of no effect and shall not affect the enforceability or validity of the remainder of this AGREEMENT or any of its provisions; provided, however, the PARTIES shall use their respective reasonable efforts to mutually agree to replace the invalid provisions in a manner that best accomplishes the original intentions of the PARTIES.

20.3 Waivers. Any term or condition of this AGREEMENT may be waived at any time by the PARTY that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the PARTY waiving such term or condition. Neither the waiver by any PARTY of any term or condition of this AGREEMENT nor the failure on the part of any PARTY, in one or more instances, to enforce any of the provisions of this AGREEMENT or to exercise any right or privilege, shall be deemed or construed to be a waiver of such term or condition for any similar instance in the future or of any subsequent breach hereof. All rights, remedies, undertakings, obligations and agreements contained in this AGREEMENT shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

20.4 Entire Agreement; Amendments. This AGREEMENT (together with any agreements between the PARTIES expressly contemplated to be entered into by this AGREEMENT) sets forth the entire agreement and understanding between the PARTIES as to the subject matter hereof and supersedes all agreements or understandings, verbal or written, made between FIOCRUZ and PROTALIX before the EXECUTION DATE with respect to the subject matter hereof. All Confidential Information disclosed between FIOCRUZ and PROTALIX prior to the Effective Date will be deemed to have been disclosed pursuant to and under this AGREEMENT. None of the terms of this AGREEMENT shall be amended, supplemented or modified except in writing signed by the PARTIES.

20.5 Survival. The provisions of Articles 1, 4.3, 4.6, 4.7, 8.6, 9 (for any payment obligations incurred during the TERM until the date of termination), 10, 11, 12.6, 12.7, 13, 14, 15, 16, 17, 19 and 20, as well as (i) any other Articles, Exhibits, Schedules or Appendices or defined terms referred to in such Articles necessary to give them effect and (ii) any other provision that by its terms expressly survives termination of this AGREEMENT, shall survive termination of this AGREEMENT and remain in force until discharged in full. Furthermore, any other provisions required to interpret and enforce the PARTIES' rights and obligations or to wind up their outstanding obligations under this AGREEMENT shall survive to the extent required, including any payment obligations incurred during the Term or pursuant to any surviving Article.

20.6 Assignment; Binding Effect. Neither this AGREEMENT nor any rights or obligations of FIOCRUZ in, to or under this AGREEMENT may be assigned or otherwise transferred by FIOCRUZ without the prior written consent of PROTALIX. For purposes of this AGREEMENT, an "assignment" includes any change of control of FIOCRUZ (as such term is defined in the definition of AFFILIATES) or assignment by operation of LAW. PROTALIX may assign this AGREEMENT or any of its rights or obligations hereunder, in whole or in part, with the prior consent of FIOCRUZ (such consent not to be unreasonably withheld or delayed); provided that, for the avoidance of doubt, no such consent of FIOCRUZ shall be required for an assignment in connection with a change of control (as such term is defined in the definition of AFFILIATES), merger or reorganization of PROTALIX or any of its AFFILIATES, or a sale or other transfer by PROTALIX or any of its AFFILIATES of all or substantially all of the assets or business to which this AGREEMENT relates. Subject to the foregoing, this AGREEMENT shall be binding upon and inure to the benefit of the PARTIES and their successors, respective heirs, and legal representatives. Any purported assignment in violation of this Article 20.6 shall be void *ab initio*. Any permitted assignee shall assume all obligations of its assignor under this AGREEMENT. Notwithstanding the foregoing, should Bio-Manguinhos become a company controlled by FIOCRUZ (Empresa Brasileira de Biotecnologia em Saúde - Bio-Manguinhos), both parties consent that this agreement may be transferred to such company at FIOCRUZ's sole discretion without Protalix written consent.

20.7 Independent Contractor. The relationship between the PARTIES is that of independent contractors. The PARTIES are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties. Neither PARTY has the authorization or right hereunder to make any representations, enter into any agreements or assume any other obligations on behalf of the other PARTY.

20.8 Publicity. FIOCRUZ shall not make (and shall cause its Affiliates not to make) any press release or public statement (written or oral) concerning the terms of, or events related to, this AGREEMENT or concerning PROTALIX, the PRODUCT, COMPOUND, DRUG SUBSTANCE, SUPPLIED MATERIALS, or PROTALIX TECHNOLOGY, without the prior written approval of PROTALIX, except where such statement is required by Brazilian LAW. In the case of any press release or public statement (written or oral) that is required by Brazilian LAW, FIOCRUZ shall use all reasonable efforts to give PROTALIX sufficient advance notice of the text of any such public statement, so that PROTALIX will have the opportunity to comment upon the statement, and give due consideration to any of PROTALIX's comments on such text.

20.9 Notices. All notices, consents, approvals, requests or other communications required hereunder given by one PARTY to the other hereunder shall be in writing and made by registered or certified air mail, facsimile, express overnight courier or delivered personally to the following addresses of the respective PARTIES:

If to PROTALIX:
Protalix Ltd.
2 Snunit Street
Science Park
P.O.B 455
Carmiel 20100, Israel
Attention: Chief Executive Officer
Facsimile: 972-4-988-9489

If to FIOCRUZ:
Fiocruz
Bio-Manguinhos
Pavilhão Rocha Lima - 6 andar
Avenida Brasil, 4365, Manguinhos
Rio de Janeiro, CEP: 21040-360
Brazil
Attention: Bio-Manguinhos Director
Facsimile: + 55 21 3882-7176

Notices hereunder shall be deemed to be effective (a) upon receipt if personally delivered, (b) on the tenth (10th) Business Day following the date of mailing if sent by registered or certified air mail and (c) on the first (1st) Business Day following the date of transmission or delivery to the overnight courier if sent by facsimile or overnight courier. A PARTY may change its address listed above by sending notice to the other PARTY in accordance with this Article 20.9.

20.10 Third Party Beneficiaries. Except for the rights of PERSONS not a PARTY to this AGREEMENT to indemnification pursuant to Article 16 (which is intended to benefit such PERSONS), none of the provisions of this AGREEMENT shall be for the benefit of or enforceable by any Third PARTY, including any creditor of any PARTY. No Third PARTY shall obtain any right under any provision of this AGREEMENT or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against any PARTY.

20.11 Subcontractors. FIOCRUZ shall not use any subcontractors to perform its obligations or exercise its rights hereunder, without the prior written consent of PROTALIX. PROTALIX may use one or more of its Affiliates or any reasonably able Third PARTIES to exercise its rights or perform its obligations hereunder (including each other). Despite any such subcontracting the PARTIES shall remain liable hereunder for the performance of all of its obligations hereunder (including the payment of any amounts due hereunder).

20.12 Headings. Headings in this AGREEMENT are included herein for ease of reference only and shall have no legal effect.

20.13 Language. This AGREEMENT has been prepared in the English language and has been translated into the Portuguese language and the Portuguese language version shall control all questions of interpretation and performance hereof. If there is any difference in meaning between any portion of the English version and any other version, the Portuguese version shall prevail. Unless otherwise specifically required by Brazilian LAW or by written agreement of the PARTIES or as otherwise provided herein, all notices and other communications required or permitted under this AGREEMENT shall be made in the English language.

[Signature Page Follows]

IN WITNESS WHEREOF the PARTIES hereto have caused this AGREEMENT to be executed by their duly authorized officers upon the date set out below.

Fundação Oswaldo Cruz
(on behalf of itself and the Immunobiological
Technology Institute (Bio-Manguinhos))

By: /s/ Paulo Gadelha

Name: Paulo Gadelha
Title: President

Date: _____

Protalix Ltd.

By: /s/ David Aviezer

Name: David Aviezer
Title: President and CEO

Date: _____

[Signature Page to Technology Transfer and Supply Agreement]

APPENDIX I

PROTALIX TECHNOLOGY (INCLUDING SPECIFICATIONS)

[***]

[***] Redacted pursuant to confidential treatment request.

APPENDIX II

TECHNOLOGY TRANSFER

[***]

[***] Redacted pursuant to confidential treatment request.

APPENDIX III

FORM OF ACCEPTANCE CERTIFICATE

ACCEPTANCE CERTIFICATE

[DATE]

RE: Completion of Technology Transfer Stage [#]

Reference is hereby made to the Technology Transfer Agreement by and between PROTALIX LTD., a limited liability company incorporated under the laws of Israel with offices located at 2 Snunit Street, Science Park, P.O.B 455, Carmiel 20100, Israel ("Protalix") and FUNDAÇÃO OSWALDO CRUZ, an agency of the Brazilian Ministry of Health organized under the laws of Brazil, including its manufacturing unit "BIO-MANGUINHOS", with registered offices at Avenida Brasil, 4365, Manguinhos, Rio de Janeiro, RJ, Cep 21045-900, Brazil, CGC NI 33.781.055/0001-35 (the "Agreement"). All capitalized terms contained herein shall have the meaning ascribed to such terms in the Agreement. Pursuant to the Agreement, PROTALIX and FIOCRUZ hereby acknowledge and agree that (i) the COMPLETION REQUIREMENTS of STAGE [X] of the TECHNOLOGY TRANSFER have been achieved, (ii) PROTALIX has fulfilled its obligations with respect to STAGE [X], including the TECHNOLOGY TRANSFER, supply of the SUPPLIED MATERIALS, and any technical assistance and training for such STAGE, and (iii) STAGE [X] is now complete and the Parties can proceed to STAGE [X+1].

PROTALIX LTD.	FUNDAÇÃO OSWALDO CRUZ
By:	By:
Print Name:	Print Name:
Date:	Date:

[***]

[***] Redacted pursuant to confidential treatment request.

APPENDIX V

PFIZER APPROVAL

To
Agência Nacional de Vigilância Sanitária (ANVISA/MS)

DECLARATION OF IMPORT AUTHORIZATION
BY LEGAL ENTITY WHICH DOES NOT HOLD REGULARIZATION BEFORE ANVISA
(Legal Basis: RDC Nº 81/08 - CHAPTER VII - ITEM 7B)

REFERENCE: Import License/IL nº _____/_____-_____

The company Laboratórios PFIZER Ltda., with (address), duly regularized before ANVISA - Agência Nacional de Vigilância Sanitária under Nº _____, represented by its Legal Representative _____ and Legal Responsible _____, and by its Technical Responsible _____, undersigned, grants authorization to import, directly from its supplier Protalix Ltd., the product indicated below, and which holds the regularization document before Ministério da Saúde/Agência Nacional de Vigilância Sanitária.

Authorized Importer:	Fiocruz - Instituto de Tecnologia em Imunobiológicos, Bio-Manguinhos CNPJ nº 33.781.055/0015-30

Description of the health product:	**Registration nº at ANVISA**	**Term**
_____	_____	_____

In compliance with the determination of RDC nº 81/08, we authorize exclusively the importer mentioned above to use the abovementioned register, and, therefore, its transfer is prohibited.

We expressly assume the commitment to and compliance with the standards and procedures of health legislation, as well as the science of the penalties to which we will be subject, pursuant to Law No. 6437, August 1977.

Legal Representative: _____

Legal Responsible:_____

Technical Responsible: _____

Valid for 90 days from issuance

Rio de Janeiro, _____.

_____ Legal Representative

_____ Legal Responsible

_____
Technical Responsible

[***]

[***] Redacted pursuant to confidential treatment request.

APPENDIX VII

ACCOUNT INFORMATION

[***]

[***] Redacted pursuant to confidential treatment request.

[***]

[***] Redacted pursuant to confidential treatment request.

EXHIBIT A

AMINO ACID SEQUENCE FOR DRUG SUBSTANCE

	EFARPCIPKS	FGYSSVVCVC	NATYCDSFDP	PTFPALGTFS	RYESTRSGRR	MELSMGPIQA	
61	NHTGTGLLLT	LQPEQKFQKV	KGFGGAMTDA	AALNILALSP	PAQNLLLKSY	FSEEGIGYNI	
121	IRVPMASCDF	SIRTYTYADT	PDDFQLHNFS	LPEEDTKLKI	PLIHRALQLA	QRPVSLLASP	
181	WTSPTWLKTN	GAVNGKGSLK	GQPGDIYHQT	WARYFVKFLD	AYAEHKLQFW	AVTAENEPSA	
241	GLLSGYPFQC	LGFTPEHQRD	FIARDLGPTL	ANSTHHNVRL	LMLDDQRLLL	PHWAKVVLTD	
301	PEAAKYVHGI	AVHWYLDFLA	PAKATLGETH	RLFPNTMLFA	SEACVGSKFW	EQSVRLGSWD	
361	RGMQYSHSII	TNLLYHVVGW	TDWNLALNPE	GGPNWVRNFV	DSPIIVDITK	DTFYKQPMFY	
421	HLGHFSKFIP	EGSQRVGLVA	SQKNDLDAVA	LMHPDGSAVV	VVLNRSSKDV	PLTIKDPAVG	
481	FLETISPGYS	IHTYLWHRQD	LLVDTM				

EXHIBIT B

PROTALIX PATENT SCHEDULE

[***]

[***] Redacted pursuant to confidential treatment request.

EXHIBIT C

APPLICABLE TAXES AND FEES

A [***]% tax will be withheld from payments for services made by FIOCRUZ pursuant to Section 7.4.5.

There are no withholding or other taxes applicable to any payments required to be made by FIOCRUZ under this AGREEMENT, including those made for the purchase of PRODUCTS during each STAGE of the TECHNOLOGY TRANSFER.

[***] Redacted pursuant to confidential treatment request.

[***] Represents material that has been omitted and will be filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment under Rule 24b-2 of the Securities and Exchange Act of 1934, as amended.

Binding Term Sheet between Chiesi Farmaceutici S.p.A. ("Chiesi") and Protalix Ltd. ("Protalix") for amending the U.S. and Ex-U.S. Exclusive License and Supply Agreements

This binding term sheet ("Term Sheet") is intended to advance the discussions between Protalix and Chiesi and to create alignment between the two companies on the terms and structure of a potential amendment to the Exclusive U.S. License and Supply Agreement, dated July 23, 2018 ("Chiesi US ELSA"), and the Exclusive License and Supply Agreement, dated October 17, 2017 ("Chiesi ex-US ELSA," and together with the Chiesi US ELSA, the "Chiesi ELSAs"). This Term Sheet is intended to be and shall be construed only as a summary of the indication of the interest of the Parties in such a possible amendment.

Scope	This Term Sheet is made between Chiesi and Protalix solely for purposes of reaching a settlement regarding the payment of certain milestones under the Chiesi ELSAs. Capitalized terms used herein shall have the meanings given to them in the Chiesi ELSAs.
Consideration and Milestone Payments	Chiesi shall pay Protalix $10,000,000 prior to June 30, 2021 (the "Payment"). In exchange for the Payment, the Event Milestone Payment associated with [***] in the Chiesi ex-US ELSA, due upon regulatory approval in the EU as provided in the Chiesi ex-US ELSA, will be reduced by $25,000,000. All other Event Milestone Payments in the Chiesi ELSAs shall remain unchanged. [***]
Other Matters	The parties will negotiate in good faith the content and the terms of that certain [***], in order to reach an agreement on mutually acceptable terms at the earliest possible date.
Binding Effect	Upon both Parties' execution of this Term Sheet, this Term Sheet shall be binding. Unless and until this Term Sheet is finalized and becomes binding, it shall not be publicly disclosed and shall remain confidential.
Confidentiality	This Term Sheet is Confidential Information of the Parties under the confidentiality provisions set forth in the Chiesi ELSAs. Unless and until this Term Sheet is finalized and becomes binding, it shall not be publicly disclosed and shall remain confidential

[***] Redacted pursuant to confidential treatment request.

Governing Law	This Agreement shall be governed by and construed in accordance with the substantive Laws of the State of New York, without regard to conflicts of law rules.
Other Agreements	There are no other agreements, understandings, or amendments being discussed with respect to this Term Sheet, and the terms set forth herein represents the totality of the agreements and understandings of the parties.

[Signatures appear on following page]

Chiesi Farmaceutici S.p.A. ("Chiesi")

By:	/s/ Ugo Di Francesco
Title:	CEO
Name:	Ugo Di Francesco
Date:	May 13, 2021

Protalix Ltd. ("Protalix")

By:	/s/ Eyal Rubin	/s/ Dror Bashan
Title:	CFO	CEO
Name:	Eyal Rubin	Dror Bashan
Date:	5/13/2021	5/13/2021

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: May 14, 2021

/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: May 14, 2021

/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 March 31, 2021 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: May 14, 2021

/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 March 31, 2021 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: May 14, 2021

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