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, 2014

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)

Florida	**65-0643773**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2 Snunit Street Science Park POB 455 Carmiel, Israel	
(Address of principal executive offices)	**20100 (Zip Code)**

+972-4-988-9488
(Registrant's telephone number, including area code)

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "large accelerated filer" and "accelerated filer" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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

On May 1, 2014, approximately 93,606,460 shares of the Registrant's common stock, $0.001 par value, were outstanding.

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Except where the context otherwise requires, the terms, "we," "us," "our" or "the Company," refer to the business of Protalix BioTherapeutics, Inc. and its consolidated subsidiaries, and "Protalix" or "Protalix Ltd." refers to the business of Protalix Ltd., our wholly-owned subsidiary and sole operating unit.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

The statements set forth under the captions "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors," and other statements included elsewhere in this Quarterly Report on Form 10-Q, which are not historical, constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to our company or our subsidiaries or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

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

- risks related to the commercialization efforts for taliglucerase alfa in the United States, Israel, Brazil and other countries;
- the risk of significant delays in the commercial introduction of taliglucerase alfa in the United States, Brazil, Israel and other markets as planned;
- risks related to the acceptance and use of taliglucerase alfa or any of our product candidates, if approved, by physicians, patients and third-party payors;
- our ability to supply drug product pursuant to our supply arrangement with the Brazilian Ministry of Health, or the Brazilian MOH;
- the risk that we will not be able to develop a successful sales and marketing organization for taliglucerase alfa in Israel or for any other product candidate in a timely manner, if at all;
- failure or delay in the commencement or completion of our preclinical studies and clinical trials which may be caused by several factors, including: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; inability to monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; 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, that our product candidates will not have the desired effects or include undesirable side effects or other unexpected characteristics;
- our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services;
- delays in the approval or the potential rejection of any application filed with or submitted to the regulatory authorities reviewing taliglucerase alfa outside of the United States, Israel, Brazil and other countries in which taliglucerase alfa is already approved;
- our ability to establish and maintain strategic license, collaboration and distribution arrangements, and to manage our relationships with Pfizer Inc., with Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian MOH, or any other collaborator, distributor or partner;

- risks relating to our ability to finance our research programs, the expansion of our manufacturing capabilities and the ongoing costs in the case of delays in regulatory approvals for taliglucerase alfa outside of the United States, Israel, Brazil and other countries in which taliglucerase alfa is already approved;
- delays in our preparation and filing of applications for regulatory approval of our other product candidates in the United States, the European Union and elsewhere;
- our expectations with respect to the potential commercial value of our product and product candidates;
- the risk that products that are competitive to our product candidates may be granted orphan drug status in certain territories and, therefore, will be subject to potential marketing and commercialization restrictions;
- the impact of development of competing therapies and/or technologies by other companies;
- any lack of progress of our research and development activities and our clinical activities with respect to any product candidate;
- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;
- potential product liability risks, and risks of securing adequate levels of product liability and clinical trial insurance coverage;
- risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our 2018 convertible notes, or any other indebtedness;
- the possibility of infringing a third party's patents or other intellectual property rights;
- the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third parties;
- risks relating to biosimilar legislation and/or healthcare reform in the United States or elsewhere; and
- the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the U.S. Food and Drug Administration, or the FDA, or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

These forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These and other risks and uncertainties are detailed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2013, and are described from time to time in the reports we file with the U.S. Securities and Exchange Commission, or the Commission.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2014	December 31, 2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 77,690	$ 86,398
Accounts receivable - Trade	1,735	2,091
Other assets	2,609	1,457
Inventories	6,527	7,957
Total current assets	88,561	97,903
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,622	1,578
PROPERTY AND EQUIPMENT, NET	13,098	13,711
DEFERRED CHARGES	135	141
Total assets	$ 103,416	$ 113,333
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,639	$ 5,254
Other	14,533	12,073
Deferred revenues	7,609	9,369
Total current liabilities	26,781	26,696
LONG TERM LIABILITIES:		
Convertible notes	67,151	67,048
Deferred revenues	40,655	41,796
Liability in connection with collaboration operation		2,371
Liability for employee rights upon retirement	2,407	2,368
Total long term liabilities	110,213	113,583
Total liabilities	136,994	140,279
COMMITMENTS		
CAPITAL DEFICIENCY	(33,578)	(26,946)
Total liabilities net of capital deficiency	$ 103,416	$ 113,333

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 data)
(Unaudited)

	Three Months Ended	
	March 31, 2014	**March 31, 2013**
REVENUES	$ 6,696	$ 3,568
COMPANY'S SHARE IN COLLABORATION AGREEMENT	687	400
COST OF REVENUES	(4,073)	(971)
GROSS PROFIT	3,310	2,997
RESEARCH AND DEVELOPMENT EXPENSES (1)	(8,152)	(7,754)
Less – grants and reimbursements	2,085	2,431
RESEARCH AND DEVELOPMENT EXPENSES, NET	(6,067)	(5,323)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(3,711)	(2,103)
OPERATING LOSS	(6,468)	(4,429)
FINANCIAL EXPENSES	(915)	(14)
FINANCIAL INCOME	38	122
FINANCIAL INCOME (EXPENSES) – NET	(877)	108
NET LOSS FOR THE PERIOD	$ (7,345)	$ (4,321)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ 0.08	$ 0.05
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	92,686,638	92,184,220
(1) Includes share-based compensation	428	870
(2) Includes share-based compensation	242	497

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

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

	Common Stock (1)	Common Stock	Additional paid–in capital	Accumulated deficit	Total
	Number of shares	Amount			
Balance at December 31, 2012	**93,489,809**	**$ 93**	**$ 180,145**	**$ (183,595)**	**$ (3,357)**
Changes during the three-month period ended March 31, 2013:					
Share-based compensation related to stock options			347		347
Share-based compensation related to restricted stock award			1,020		1,020
Exercise of options granted to employees	12,421	1	27		28
Net loss for the period				(4,321)	(4,321)
Balance at March 31, 2013	**93,502,230**	**$ 94**	**$ 181,539**	**$ (187,916)**	**$ (6,283)**
Balance at December 31, 2013	**93,551,098**	**$ 94**	**$ 184,345**	**$ (211,385)**	**$ (26,946)**
Changes during the three-month period ended March 31, 2014:					
Share-based compensation related to stock options			162		162
Share-based compensation related to restricted stock award			508		508
Exercise of options granted to employees (includes net exercise)	55,362	*	43		43
Net loss for the period				(7,345)	(7,345)
Balance at March 31, 2014	**93,606,460**	**94**	**185,058**	**(218,730)**	**(33,578)**

* Represents an amount less than $1.

(1) Common Stock, $0.001 par value; Authorized – as of March 31, 2014 and 2013 - 150,000,000 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, 2014	**March 31, 2013**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,345)	$ (4,321)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	670	1,367
Depreciation and write down of fixed assets	828	926
Financial expense (income), net (mainly exchange differences)	14	(78)
Changes in accrued liability for employee rights upon retirement	50	60
Gain on amounts funded in respect of employee rights upon retirement	(1)	(19)
Amortization of debt issuance costs and debt discount	109	-
Changes in operating assets and liabilities:		
Decrease in deferred revenues (including non-current portion)	(2,901)	(2,740)
Increase in accounts receivable and other assets	(744)	(42)
Decrease (increase) in inventories	1,430	(1,734)
Decrease in accounts payable and accruals (including long term)	(450)	(3,005)
Net cash used in operating activities	$ (8,340)	$ (9,586)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (263)	$ (642)
Investment in restricted deposit	(57)	
Amounts funded in respect of employee rights upon retirement, net	(50)	(47)
Net cash used in investing activities	$ (370)	$ (689)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Exercise of options	$ 31	
Net cash provided by financing activities	$ 31	
EFFECT OF EXCHANGE RATE CHANGES ON CASH	$ (29)	$ 110
NET DECREASE IN CASH AND CASH EQUIVALENTS	(8,708)	(10,165)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	86,398	52,035
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 77,690	$ 41,870

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, 2014	**March 31, 2013**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 138	$ 815
Exercise of options granted to employees	$ 12	$ 28

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the "Company"), and its wholly-owned subsidiary, Protalix Ltd., are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company's proprietary ProCellEx® protein expression system ("ProCellEx"). In September 2009, Protalix Ltd. formed another wholly-owned subsidiary under the laws of the Netherlands, Protalix B.V., in connection with the European Medicines Agency ("EMA") application process in the European Union. The Company's two subsidiaries are referred to collectively herein as the "Subsidiaries."

On May 1, 2012, the U.S. Food and Drug Administration ("FDA") approved taliglucerase alfa for injection, the Company's first approved drug product, as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Taliglucerase alfa is a proprietary, recombinant form of glucocerebrosidase (GCD) that the Company developed using ProCellEx. Taliglucerase alfa was also approved by the Israeli Ministry of Health (the "Israeli MOH") in September 2012, by the Brazilian Ministry of Health (the "Brazilian MOH") in March 2013 and by the applicable regulatory authorities of certain other countries. Taliglucerase alfa is the first plant cell-based recombinant therapeutic protein approved by the FDA or any other major regulatory authority.

Taliglucerase alfa is being marketed in the United States under the brand name ELELYSO™ by Pfizer Inc. ("Pfizer"), the Company's commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd. and Pfizer (the "Pfizer Agreement"). The Company, through Protalix Ltd., markets ELELYSO in Israel, and in Brazil under the brand name UPLYSO.

Protalix Ltd. granted Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa under the Pfizer Agreement, but retained those rights in Israel and, since 2014, in Brazil (see below). The Company has agreed to a specific allocation between Protalix Ltd. and Pfizer regarding the responsibilities for the continued development efforts for taliglucerase alfa. To date, the Company has received an upfront payment of $60.0 million in connection with the execution of the Pfizer Agreement and shortly thereafter an additional $5.0 million clinical development-related milestone payment. The Company received during 2012 an additional $25.0 million milestone payment in connection with the FDA's approval of taliglucerase alfa in the United States. The agreement provides that the Company share with Pfizer the net profits or loss related to the development and commercialization of taliglucerase alfa on a 40% and 60% basis, respectively, except with respect to the profits or losses related to commercialization efforts in Israel and Brazil, where the Company retained exclusive marketing rights. In calculating the net profits or losses under the agreement, there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold.

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

On June 18, 2013, Protalix Ltd. entered into a Supply and Technology Transfer Agreement (the "Brazil Agreement") with Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian MOH, for taliglucerase alfa. The brand name for taliglucerase alfa in Brazil is UPLYSO™. The first term of the technology transfer is seven years and the agreement may be extended for an additional five-year term, as needed, to complete the technology transfer. The technology transfer is designed to be effected in four stages and is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high quality, and cost effective supply of taliglucerase alfa. Under the agreement, Fiocruz has committed to purchase at least approximately $40 million worth of taliglucerase alfa during the first two years of the agreement. In subsequent years, Fiocruz is required to purchase at least approximately $40 million worth of taliglucerase alfa per year. Additionally, Protalix Ltd. is not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately $280 million worth of taliglucerase alfa. The Brazil agreement became effective during the first quarter of 2014.

During the three months ended March 31, 2014, the Company recorded revenues of approximately $3.5 million from the sale of products to Fiocruz.

To facilitate the arrangement with Fiocruz, Pfizer amended its exclusive license and supply agreement with Protalix Ltd. The amendment provides for the transfer of the commercialization and other rights to taliglucerase alfa in Brazil back to Protalix Ltd. As consideration for the transfer of the commercialization and supply rights, Protalix Ltd. agreed to pay Pfizer a maximum amount of approximately $12.5 million from its net profits (as defined in the license and supply agreement) per year. Pfizer has also agreed to perform certain transitional services in Brazil on Protalix Ltd.'s behalf in connection with the supply of taliglucerase alfa to Fiocruz.

Protalix Ltd. is required to pay a fee equal to 5% of the net proceeds generated in Brazil to its agent for services provided in assisting Protalix Ltd. complete the Brazil Agreement pursuant to an agency agreement between Protalix Ltd. and the agent. The agency agreement will remain in effect with respect to the Brazil Agreement until the termination thereof.

In addition to the approvals from the FDA, the Israeli MOH and the Brazilian MOH, marketing approval has been granted to UPLYSO in Mexico, Chile and Uruguay. In addition, the Company is cooperating with Pfizer in its efforts to obtain marketing approval for taliglucerase alfa in additional countries and jurisdictions. Currently, marketing authorization applications have been filed in a number of countries.

Currently, patients are being treated with taliglucerase alfa on a commercial basis in the United States, Brazil, Chile and Israel. In addition, patients are being treated globally through the Company's clinical trials and related studies, compassionate use programs and other programs. On July 13, 2010, the Company announced that the French regulatory authority had granted an Autorisation Temporaire d'Utilisation (ATU), or Temporary Authorization for Use, for taliglucerase alfa for the treatment of Gaucher disease.

An ATU is the regulatory mechanism used by the French Health Products and Safety Agency to make non-approved drugs available to patients in France when a genuine public health need exists. This ATU allows Gaucher patients in France to receive treatment with taliglucerase alfa before marketing authorization for the product is granted in the European Union. Payment for taliglucerase alfa has been secured through government allocations to hospitals. In addition, taliglucerase alfa is currently being provided to Gaucher patients under special access agreements or named patient provisions in other countries.

In addition to taliglucerase alfa, the Company is working on the development of certain other products using ProCellEx.

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

In addition to the approval of taliglucerase alfa for marketing in the United States, Israel, Brazil, Mexico and other countries, successful completion of the Company's development programs and its transition to normal operations is dependent upon obtaining the foreign regulatory approvals required to sell its products internationally. A substantial amount of time may pass before the Company achieves a level of revenues adequate to support its operations, if at all, and the Company expects to incur substantial expenditures in connection with the regulatory approval process for each of its product candidates during their respective developmental periods.

Obtaining marketing approval with respect to any product candidate in any country is directly dependent on the Company's ability to implement the necessary regulatory steps required to obtain such approvals. The Company cannot reasonably predict the outcome of these activities.

b. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP") for interim financial information. Accordingly, they do not include all of the information and notes required by GAAP for annual financial statements. In the opinion of management, all adjustments (of a normal recurring nature) considered necessary for a fair statement of the results for the interim periods presented have been included. Operating results for the interim period are not necessarily indicative of the results that may be expected for the full year.

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2013, filed by the Company with the Securities and Exchange Commission. The comparative balance sheet at December 31, 2013 has been derived from the audited financial statements at that date.

c. Net loss per share

Basic and diluted loss per share ("LPS") are computed by dividing net loss by the weighted average number of shares of the Company's Common Stock, par value $0.001 per share (the "Common Stock") outstanding for each period.

Diluted LPS does not include 7,471,571 and 18,913,153 shares of Common Stock underlying outstanding options and restricted shares of Common Stock and shares issuable upon conversion of the convertible notes (issued in September 2013) for the three months ended March 31, 2013 and 2014, respectively, because the effect would be anti-dilutive.

NOTE 2 - INVENTORIES

Inventory at March 31, 2014 and December 31, 2013 consisted of the following:

	March 31, 2014	December 31, 2013
	(U.S. dollars in thousands)	
Raw materials	$ 2,076	$ 2,342
Work in progress	170	92
Finished goods	4,281	5,523
Total inventory	$ 6,527	$ 7,957

During the three months ended March 31, 2014, the Company recorded approximately $1.1 million for write-down of inventory under cost of revenues.

NOTE 3 – FAIR VALUE MEASUREMENT

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received from the sale of an asset, or paid to transfer a liability, in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

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

NOTE 4 – STOCK TRANSACTIONS

During the three months ended March 31, 2014, the Company issued a total of 55,362 shares of Common Stock in connection with the exercise of a total of 56,122 options by certain employees of the Company. The aggregate proceeds in connection with such exercises totaled approximately $43,000.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the consolidated financial statements and the related notes included elsewhere in this Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2013. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2013 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx® protein expression system, or ProCellEx. Using our ProCellEx system, we are developing a pipeline of proprietary, biobetter and biosimilar versions of recombinant therapeutic proteins, based on our plant cell-based expression technology, that primarily target large, established pharmaceutical markets and that rely upon known biological mechanisms of action. Our initial commercial focus has been on complex therapeutic proteins, including proteins for the treatment of genetic disorders, such as Gaucher disease and Fabry disease. We believe ProCellEx will enable us to develop proprietary recombinant proteins that are therapeutically equivalent or superior to existing recombinant proteins currently marketed for the same indications. Because we are primarily targeting biologically equivalent versions of highly active, well-tolerated and commercially successful therapeutic proteins, we believe our development process is associated with relatively less risk compared to other biopharmaceutical development processes for completely novel therapeutic proteins. We are now also applying the unique properties of our ProCellEx system for the oral delivery of therapeutic proteins, with the first two product candidates being glucocerebrosidase and antiTNF fusion protein, and we are performing research focused on the oral delivery of antibodies.

On May 1, 2012, the U.S. Food and Drug Administration, or the FDA, approved for sale our first commercial product, taliglucerase alfa for injection, which is being marketed in the United States and Israel under the brand name ELELYSO™, as an enzyme replacement therapy, or ERT, for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Subsequently, taliglucerase alfa was approved by the Brazilian National Health Surveillance Agency (Agencia Nacional de Vigilancia Sanitaria, or ANVISA) in March 2013, by the Israeli Ministry of Health, or the Israeli MOH, in September 2012, and by the applicable regulatory authorities in Uruguay, Mexico and Chile. Taliglucerase alfa will be marketed under the name UPLYSO™ in Brazil and certain other Latin American countries. Taliglucerase alfa is our proprietary, recombinant form of glucocerebrosidase, or GCD, that is produced or expressed through ProCellEx. Taliglucerase alfa is the first plant cell-based recombinant therapeutic protein to be approved by the FDA or by the regulatory authorities with jurisdiction over any substantial market. Gaucher disease is a rare and serious lysosomal storage disorder with severe and debilitating symptoms. Gaucher patients suffer from mutations in or deficiencies of GCD, an enzyme that is naturally found in human cells.

Since May 2012, taliglucerase alfa has been marketed in the United States by Pfizer Inc., or Pfizer, our commercialization partner, as provided in the exclusive license and supply agreement by and between Protalix Ltd., our wholly-owned subsidiary, and Pfizer, which we refer to as the Pfizer Agreement. We granted Pfizer an exclusive, worldwide license to develop and commercialize taliglucerase alfa under the Pfizer Agreement, but we retained those rights in Israel and in Brazil. We have agreed to a specific allocation between Protalix Ltd. and Pfizer of the responsibilities for the continued development efforts for taliglucerase alfa outside of Israel. Protalix Ltd. has been marketing taliglucerase alfa in Israel since 2013 and in Brazil since January 2014.

On June 18, 2013, we entered into a Supply and Technology Transfer Agreement, or the Brazil Agreement, with Fiocruz, for taliglucerase alfa. The agreement became effective in January 2014. The technology transfer is designed to be completed in four stages and is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high-quality, and cost-effective supply of taliglucerase alfa. The initial term of the technology transfer is seven years. Under the agreement, Fiocruz has committed to purchase at least approximately $40 million worth of taliglucerase alfa during the first two years of the term. In subsequent years, Fiocruz is required to purchase at least approximately $40 million worth of taliglucerase alfa per year. Additionally, we are not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately $280 million worth of taliglucerase alfa.

The Brazil Agreement may be extended for an additional five-year term, as needed, to complete the technology transfer. All of the terms of the arrangement, including the minimum annual purchases, will apply during the additional term. Upon completion of the technology transfer, and subject to Fiocruz receiving approval from ANVISA to manufacture taliglucerase alfa in its facility in Brazil, the agreement will enter into the final term and will remain in effect until our last patent in Brazil expires. During such period, Fiocruz will be the sole provider of this important treatment option for Gaucher patients in Brazil and shall pay us a single-digit royalty on net sales.

To facilitate the arrangement with Fiocruz, we and Pfizer agreed to an amendment of our exclusive license and supply agreement, which amendment provides for the transfer of the commercialization and other rights to taliglucerase alfa in Brazil back to us. As consideration for the transfer of the commercialization and supply rights, we agreed to pay Pfizer a maximum amount of approximately $12.5 million from its net profits (as defined in the license and supply agreement) per year. Pfizer has also agreed to perform certain transitional services in Brazil on our behalf in connection with the supply of taliglucerase alfa to Fiocruz.

We will pay a fee equal to 5% of the net proceeds generated in Brazil to our agent for services provided in assisting us complete the Brazil Agreement pursuant to an agency agreement between us and the agent. The agency agreement will remain in effect with respect to the Brazil Agreement until the termination thereof.

We are cooperating with Pfizer to obtain marketing approval for taliglucerase alfa in additional countries and jurisdictions. In addition to those countries in which taliglucerase alfa has been approved, marketing authorization applications have been filed in other countries.

In addition to naive and switch studies in adults which were successfully completed, we conducted a 12-month clinical trial of naïve and switchover pediatric patients, which was successfully completed in 2012. Based on the data from this study, an application for a supplement to the NDA for ELEYSO, allowing a pediatric use indication to be added to the product label, has recently been submitted by Pfizer to the FDA. Patients in the extension trials are still being treated with taliglucerase alfa.

Currently, patients are being treated with taliglucerase alfa on a commercial basis in the United States, Brazil, Israel and Chile. Globally, patients are being treated through our extension trials and related studies, compassionate use programs, special access agreements, named patient provisions and other programs designed to ensure that treatments are available to Gaucher patients in light of recent shortages of approved treatments. In France, Gaucher patients are being treated with taliglucerase alfa through an Autorisation Temporaire d'Utilisation (ATU), or Temporary Authorization for Use, a regulatory mechanism used by the French Health Products and Safety Agency to make non-approved drugs available to patients in France when a genuine public health need exists. In addition to the United States and France, taliglucerase alfa is currently being provided to Gaucher patients under special access agreements or named patient provisions in certain countries. Hundreds of patients, in the aggregate, have been treated with taliglucerase alfa.

In addition to taliglucerase alfa, we are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates:

(1) PRX-102, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, currently in a phase I/II clinical trial for which the first patient was treated in December 2012. We expect to complete patient recruitment and report interim results by the end of 2014, and to report final results during the first half of 2015.

(2) PRX-112, an orally administered glucocerebrosidase enzyme for the treatment of Gaucher patients utilizing oral delivery of the recombinant GCD enzyme produced and encapsulated within carrot cells, the subject of a phase I clinical study. We announced positive results from the phase I trial in February 2014. We expect to commence a phase IIa clinical trial treating 10 Gaucher patients for 28 days within the next few months.

(3) PRX-106, our oral antiTNF product candidate which is being developed as an orally-administered treatment for immune mediated disorders using plant cells as a natural capsule for the expressed protein. We are currently conducting preclinical studies on oral antiTNF for several attractive indications, and we expect to initiate a phase I clinical trial of oral anti TNF for the oral treatment of autoimmune diseases in 2014.

(4) PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1 under development for the treatment of cystic fibrosis, to be administered by inhalation. We held a pre-IND meeting with the FDA in 2012, and plan to file an IND with the FDA following the completion of toxicology studies in 2014.

Except for the rights to commercialize taliglucerase alfa worldwide (other than Brazil and Israel), which we licensed to Pfizer, we hold the worldwide commercialization rights to all of our proprietary development candidates. We have built an internal marketing team designed to serve the Israeli and Brazilian market for taliglucerase alfa and we intend to establish internal commercialization and marketing teams for our other product candidates in North America, the European Union and in other significant markets, including Israel, subject to required marketing approvals, as the need arises. In addition, we continuously evaluate potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutes.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing in this Quarterly Report. There have not been any changes to our significant accounting policies since the Annual Report on Form 10-K for the year ended December 31, 2013.

The discussion and analysis of our financial condition and results of operations is based on our financial statements, which we prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Results of Operations

Three months ended March 31, 2014 compared to the three months ended March 31, 2013

Revenues

We recorded revenues of $6.7 million during the three months ended March 31, 2014, an increase of $3.1 million, or 88%, from revenues of $3.6 million for the three months ended March 31, 2013. Revenues for the three months ended on March 31, 2014 included $3.5 million of products sold in Brazil, $1.1 million in Israel and $1.0 million in connection with products we delivered at cost to Pfizer under the Pfizer Agreement. Revenues also represent a pro rata amortization of the $65.0 million upfront and milestone payments of $1.1 million in each quarterly period.

Our share in the Collaboration Agreement

We recorded revenue of $687,000 as our share of net income from the collaboration under the Pfizer Agreement during the three months ended March 31, 2014, an increase of $287,000, or 72%, from revenue of $400,000 for the three months ended March 31, 2013. Our share in the collaboration agreement recorded during the three months ended March 31, 2014 represents our 40% share of the net income generated during the period, which was primarily the result of revenues generated by Pfizer in the United States which exceeded the expenses during such period. Under the terms and conditions of the Pfizer Agreement, we record income or loss equal to 40% of the profit or loss realized from sales of taliglucerase alfa and related expenses incurred based on reports we receive from Pfizer summarizing the results of the collaborative activities under the Pfizer Agreement for the applicable period.

Cost of Revenues

Cost of revenues was $4.1 million for the three months ended March 31, 2014, an increase of $3.1 million from cost of revenues of $971,000 for the three months ended March 31, 2013. Cost of revenues for the three months ended March 31, 2014 consists of the costs of the $1.0 million of products we delivered at cost to Pfizer under the Pfizer Agreement, write-down of inventory of $1.1 million, and certain fixed costs relating to our manufacturing facility, including rent, depreciation, salary and maintenance expenses, and to a much lesser extent, the direct cost of products we sold in Israel and Brazil for which revenues were recognized during the period.

Research and Development Expenses, Net

Research and development expenses were $8.2 million for the three months ended March 31, 2014, an increase of $398,000, or 5%, from $7.8 million for the three months ended March 31, 2013. The increase resulted primarily from an increase of $109,000 in materials and an increase of $127,000 in costs related to salaries expense. The increase also resulted from a decrease in reimbursement of expenses equal to $2.1 million in accordance with the terms and conditions of the Pfizer Agreement during the three months ended March 31, 2014 and from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor, compared to the total reimbursement of approximately $2.4 million during the three months ended March 31, 2013.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $3.7 million for the three months ended March 31, 2014, an increase of $1.6 million, or 76%, from $2.1 million for the three months ended March 31, 2013. The increase resulted primarily from sales and marketing expenses of approximately $1.0 million, primarily in connection with sales in Brazil, and an increase of $564,000 in salaries expense.

Financial Expenses and Income

Financial expenses were $877,000 for the three months ended March 31, 2014 compared to financial income of $108,000 for the three months ended March 31, 2013. Financial expenses resulted primarily from interest expense of $887,000 for the 4.5% convertible note which was partially offset by financial income which resulted primarily from interest earned on short term deposits.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures which supersedes our product sales revenue, we have not been profitable and have generated operating losses since our inception with the exception of the quarter ended on June 30, 2012 due to the $25.0 million milestone payment we received from Pfizer in connection with FDA approval of taliglucerase alfa in that period. To date, we have funded our operations primarily with proceeds equal to $31.3 million from the sale of shares of convertible preferred and ordinary shares of Protalix Ltd., and an additional $14.1 million in connection with the exercise of warrants issued in connection with the sale of such shares, through December 31, 2008. In addition, on October 25, 2007, we generated gross proceeds of $50 million in connection with an underwritten public offering of our common stock and on each of March 23, 2011 and February 22, 2012, we generated gross proceeds of $22.0 million and $27.2 million, respectively, in connection with underwritten public offerings of our common stock

In addition to the foregoing, on September 18, 2013, we completed a private placement of $69.0 million in aggregate principal amount of 4.50% convertible notes due 2018, or the Notes, including $9.0 million aggregate principal amount of Notes related to the offering’s initial purchaser’s over-allotment option, which was exercised in full.

Pfizer paid Protalix Ltd. $60.0 million as an upfront payment in connection with the execution of the Pfizer Agreement and subsequently paid to Protalix Ltd. an additional $5.0 million upon Protalix Ltd.'s meeting a certain milestone. Protalix Ltd. also received a milestone payment of $25.0 in connection with the FDA's approval of taliglucerase alfa in May 2012. Protalix Ltd. is also entitled to payments equal to 40% of the net profits earned by Pfizer on its global sales of taliglucerase alfa (except in Israel). In calculating net profits there are certain agreed upon limits on the amounts that may be deducted from gross sales for certain expenses and costs of goods sold. Pfizer has also paid Protalix Ltd. $8.3 million in connection with the successful achievement of certain milestones under the Clinical Development Agreement between Pfizer and Protalix Ltd.

We believe that the funds currently available to us as are sufficient to satisfy our capital needs for the foreseeable future.

Cash Flows

Net cash used in operations was $8.3 million for the three months ended March 31, 2014. The net loss for the three months ended March 31, 2014 of $7.3 million was further increased by a decrease of $2.9 million in deferred revenues and a decrease of $450,000 in accounts payable, but was partially offset by a decrease of $1.4 million in inventories, share based compensation of $670,000, and $828,000 in depreciation. Net cash used in investing activities for the three months ended March 31, 2014 was $370,000 and consisted primarily of purchases of property and equipment.

Net cash used in operations was $9.6 million for the three months ended March 31, 2013. The net loss for the three months ended March 31, 2013 of $4.3 million was further increased by a decrease of $2.7 million in deferred revenues, a decrease of $3.0 million in accounts payable and an increase in inventories, but was partially offset by share based compensation of $1.4 million and $926,000 in depreciation. Net cash used in investing activities for the three months ended March 31, 2013 was $689,000 and consisted primarily of purchases of property and equipment.

Future Funding Requirements

We expect to continue to incur significant expenditures in the near future. However, we anticipate that we will generate revenues to offset such losses as Pfizer's commercialization efforts for taliglucerase alfa in the United States and as our commercialization efforts for taliglucerase alfa in Brazil and Israel progress, and as taliglucerase alfa is launched by Pfizer in other countries in which taliglucerase alfa was recently approved. We also anticipate that we will generate additional revenues after additional anticipated marketing approvals of taliglucerase alfa are granted in new countries. We expect to continue to incur significant research and development expenses, including expenses related primarily to the clinical trials of PRX-102 and oral glucocerebrosidase and the advancement of our other product candidates into clinical trials.

We believe that our existing cash and cash equivalents will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for the foreseeable future. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many factors, including the progress of Pfizer's commercialization efforts for taliglucerase alfa in the United States and other countries, the progress of our commercialization efforts for taliglucerase alfa in Brazil and Israel and, if anticipated marketing approvals of taliglucerase alfa are granted in other jurisdictions, the progress of Pfizer's global commercialization efforts for taliglucerase alfa, the progress and results of our clinical trials, the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

We may need to finance our future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. We currently do not have any commitments for future external funding. We may need to raise additional funds more quickly if one or more of our assumptions prove to be incorrect or if we choose to expand our product development efforts more rapidly than we presently anticipate. We may also decide to raise additional funds even before we need them if the conditions for raising capital are favorable. Any sale of additional equity or debt securities will likely result in dilution to our shareholders. The incurrence of indebtedness would result in increased fixed obligations and could also result in covenants that would restrict our operations. Additional equity or debt financing, grants or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our planned commercialization efforts or obtain funds through arrangements with collaborators or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

Effects of Inflation and Currency Fluctuations

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the three months ended March 31, 2014 or the three months ended March 31, 2013.

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, 2014 or the three months ended March 31, 2013.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of March 31, 2014 and March 31, 2013.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Currency Exchange Risk

The currency of the primary economic environment in which our operations are conducted is the U.S. dollar. We consider the currency of the primary economic environment to be the currency in which we generate revenues and expend cash. Most of our revenues are denominated in U.S. dollars, approximately 50% of our expenses and capital expenditures are incurred in U.S. dollars, and a significant source of our financing has been provided in U.S. dollars. Since the dollar is the functional currency, monetary items maintained in currencies other than the dollar are remeasured using the rate of exchange in effect at the balance sheet dates and non-monetary items are remeasured at historical exchange rates. Revenue and expense items are remeasured at the average rate of exchange in effect during the period in which they occur. Foreign currency translation gains or losses are recognized in the statement of operations.

Approximately 35% 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 income before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Three months ended March 31,		Year ended December 31,
	2014	2013	2013
Average rate for period	3.497	3.708	3.611
Rate at period end	3.487	3.648	3.471

To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rate of the U.S. dollar against the NIS. These measures, however, may not adequately protect us from material adverse effects due to the impact of inflation in Israel.

Interest Rate Risk

Our exposure to market risk is confined to our cash and cash equivalents. We consider all short term, highly liquid investments, which include short-term deposits with original maturities of three months or less from the date of purchase, that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash, to be cash equivalents. The primary objective of our investment activities is to preserve principal while maximizing the interest income we receive from our investments, without increasing risk. We invest any cash balances primarily in bank deposits and investment grade interest-bearing instruments. We are exposed to market risks resulting from changes in interest rates. We do not use derivative financial instruments to limit exposure to interest rate risk. Our interest gains may decline in the future as a result of changes in the financial markets.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The controls evaluation was conducted under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. Disclosure controls and procedures are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Quarterly Report on Form 10-Q, is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms. Disclosure controls and procedures are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Based on the controls evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified by the Commission, and that material information relating to our company and our consolidated subsidiary is made known to management, including the Chief Executive Officer and Chief Financial Officer, particularly during the period when our periodic reports are being prepared.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of controls effectiveness to future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in internal controls

There were no changes to our internal controls over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended March 31, 2014 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2013.

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

Unregistered Sales of Equity Securities

There were no unregistered sales of equity securities during the three months ended March 31, 2014.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File Number	Exhibit	Date	
3.1	Amended and Restated Articles of Incorporation of the Company	S-4	333-48677	3.4	March 26, 1998	
3.2	Article of Amendment to Articles of Incorporation dated June 9, 2006	8-A	001-33357	3.2	March 9, 2007	
3.3	Article of Amendment to Articles of Incorporation dated December 13, 2006	8-A	001-33357	3.3	March 9, 2007	
3.4	Article of Amendment to Articles of Incorporation dated December 26, 2006	8-A	001-33357	3.4	March 9, 2007	
3.5	Article of Amendment to Articles of Incorporation dated February 26, 2007	8-A	001-33357	3.5	March 9, 2007	
3.6	Amended and Restated Bylaws of the Company	10-K	001-33357	3.6	February 28, 2013	
10.1†	Amended and Restated Agreement between Protalix Ltd. and Comercio e Serviços Ltda. dated June 17, 2013					X

10.2†	Amendment dated June 18, 2013 to the Exclusive License and Supply Agreement between Pfizer Inc. and Protalix Ltd., dated as of November 30, 2009	X
10.3†	Technology Transfer and Supply Agreement made as of June 18, 2013 by and between Protalix Ltd. and Fundação Oswaldo Cruz	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 FILE	X
101.SCH	XBRL SHEMA FILE	X
101.CAL	XBRL CALCULATION FILE	X
101.DEF	XBRL DEFINITION FILE	X
101.LAB	XBRL LABEL FILE	X
101.PRE	XBRL PRESENTATION FILE	X

SIGNATURES

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

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: May 8, 2014

By: /s/ David Aviezer
David Aviezer, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 8, 2014

By: /s/ Yossi Maimon
Yossi Maimon
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.

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.

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.

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

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

[***]

Exhibit B

Pfizer's Anti-Bribery and Anti-Corruption Principles

[***]

Exhibit C

Training Completion Form

[***]

Exhibit 10.2

Execution Copy

[***] 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.

June 18, 2013

Pfizer Inc.
235 East 42nd Street
New York, NY 10017
USA

Attention: Diem Nguyen, General Manager, Biosimilars

Re: Amendment to the Exclusive License and Supply Agreement between Pfizer Inc. and Protalix Ltd., dated as of November 30, 2009.

Dear Ms. Nguyen:

We refer to the Exclusive License and Supply Agreement between Pfizer Inc. ("Pfizer") and Protalix Ltd. ("Protalix"), dated as of November 30, 2009 (the "Agreement"). Capitalized terms used but not defined herein have the respective meanings ascribed thereto in the Agreement.

In connection with the anticipated execution by Protalix and Fundação Oswaldo Cruz ("Fiocruz") of a Technology Transfer and Supply Agreement (the "Technology Transfer Agreement"), substantially in the form attached hereto as Exhibit A, providing for the transfer of certain technology and supply of certain product by Protalix to Fiocruz, Protalix and Pfizer wish to amend the Exclusive License and Supply Agreement, pursuant to and as set forth in this letter (this "Letter Amendment").

For good and valuable consideration the receipt and sufficiency of which Pfizer and Protalix hereby acknowledge, Pfizer and Protalix hereby agree as follows:

1. Pfizer acknowledges and agrees that following execution of this Letter Amendment, notwithstanding any provision of the Agreement to the contrary, (i) Protalix shall have the exclusive rights to research, Develop or Commercialize the Drug Substance or Licensed Product in Brazil and to Manufacture (including Fill/Finish) the Drug Substance or Licensed Product for sale in Brazil, and (ii) Protalix shall have the right to enter into, and perform any of its obligations under, the Technology Transfer Agreement without obtaining any additional consents from Pfizer with respect thereto or having Pfizer participate therein.

2. In consideration for the amendments to the Agreement set forth herein, including the right for Protalix to enter into and perform the Technology Transfer Agreement as set forth in paragraph 1 of this Letter Amendment, Protalix shall pay Pfizer [***] twelve million five hundred fifty thousand dollars ($12,550,000) of Protalix's Net Profits per calendar year, commencing on [***], arising from the Commercialization of the Drug Substance and Licensed Product in Brazil, for so long as the Technology Transfer Agreement, the Agreement and this subsequent Letter Amendment remain in effect, provided that for the period of [***], Protalix shall pay Pfizer [***] eighteen million eight hundred twenty-five thousand dollars ($18,825,000) of Protalix's Net Profits arising from the Commercialization of the Drug Substance and Licensed Product in Brazil. Payments pursuant to this paragraph 2 shall be made on a quarterly basis (i.e., January 1 through March 31, April 1 through June 30, July 1 through September 30, October 1 through December 31) by Protalix within sixty (60) days of the close of each such quarter and will not be refundable. [***]. For the avoidance of doubt, (i) Protalix shall not be required pursuant to this Letter Amendment to pay to Pfizer any amount above twelve million five hundred fifty thousand dollars ($12,550,000) for any year [***], and any additional Net Profits arising from the Commercialization of the Drug Substance and Licensed Product in Brazil in any such year shall be retained by Protalix, and (ii) if Protalix's Net Profit arising from the Commercialization of the Drug Substance and Licensed Product in Brazil is less than twelve million five hundred fifty thousand dollars ($12,550,000) for any year [***], then Protalix shall only be required to pay Pfizer such lesser amount for such year (and Protalix shall not be required to pay any amounts to make up for such shortfall in such year or in any of the following years); provided that, in the event there is a net loss in Brazil, Pfizer shall have no liability to Protalix for such net loss (or any portion thereof). Pfizer and Protalix shall review the operating plan for Brazil on an annual basis, beginning with the first Joint Steering Committee meeting following approval of the Licensed Product for commercialization in Brazil. Protalix shall have the sole authority and exclusive right to determine all operating plans and strategies for the Drug Substance and Licensed Product in Brazil; provided that Protalix shall reasonably consider any comments on such plans and strategies that Pfizer may communicate through the Steering Committee or otherwise.

3. Notwithstanding anything in Section 14 of the Agreement to the contrary, Pfizer shall have the right to terminate the grant of rights to Protalix for Brazil contained herein and in the relevant Sections of the Agreement (as amended hereby) if Protalix or its designee Fiocruz fails to achieve approval of the Licensed Product in Brazil within [***] of the date of this Letter Amendment; provided that, if at the end of such [***] period, Protalix or its designee Fiocruz is continuing to take good faith commercially reasonable efforts to achieve such approval and such approval is reasonably likely to be obtained within [***] of the date of this Letter Agreement, Pfizer shall not be entitled to terminate the rights granted hereunder. Pfizer also shall have the right to terminate the grant of rights to Protalix for Brazil contained herein and in the relevant Sections of the Agreement (as amended hereby) if the Technology Transfer Agreement between Protalix and Fiocruz terminates before completion of the contemplated technology transfer. In order to terminate pursuant to this paragraph 3, Pfizer must give written notice within ten (10) days after Pfizer's termination right pursuant to this paragraph first arises.

4. For the avoidance of doubt, as used in this Letter Amendment, the term "Commercialize" includes the activities referred to in Section 1.12 of the Agreement with respect to both Drug Substance and Licensed Product.

5. Section 1.10 of the Agreement is hereby deleted in its entirety and replaced with the following: ""Capacity Cap" means the Current Capacity Cap or, after the Increased Capacity Goal is achieved, the Increased Capacity Cap."

6. Section 1.131 of the Agreement is hereby amended to add "and Brazil" immediately following the reference therein to "Israel".

7. Section 1.74 of the Agreement is hereby amended to [***].

8. Section 4.3(c)(v) of the Agreement is hereby amended to delete the reference therein to: ", including plans and strategies for[***].

9. Section 5.2(c) of the Agreement is hereby amended by deleting it in its entirety and inserting the following sentences: "With respect to the Drug Substance Manufacturing capacity of the current Protalix manufacturing facility (the "First Floor Facility"), Pfizer and Protalix shall dedicate capacity to those patients then-currently receiving Licensed Product. Allocation of Drug Substance shall be performed monthly and agreed to by the Supply Chain Committee, wherein such allocation assumes sufficient production of Drug Substance in an amount equal to [***] equivalents per month. Allocation within and outside the Territory shall occur at the final step of shared production between Pfizer and Protalix, which will depend on where the supply chain segregates in the month of allocation; that is, allocation may describe any of Drug Substance or Licensed Product, depending on a given month (such allocation priority, including as set forth herein, the "Allocation Priority"). Priority shall be given to [***]. Overages or excess inventory in a given month will be allocated to technical programs, inventory builds, and commercial sales as recommended and agreed upon by the Supply Chain Committee. Subject to and in accordance with the terms of this Section 5 and the Quality Agreement, Protalix shall supply all quantities of Drug Substance ordered by Pfizer under this Agreement for clinical and commercial use in the Field in the Territory."

10. The Agreement is hereby amended to replace the term "Allocation Percentage" with the term "Allocation Priority", for each instance such term is referenced in the Agreement.

11. Section 5.5(e) of the Agreement is hereby amended to add the following sentence at the end of such section: "Notwithstanding anything to the contrary in this Agreement [***]."

12. Section 5.6 of the Agreement is hereby amended to add the following new Section 5.6(f): "Protalix shall provide to Pfizer monthly forecasts of the quantities of Drug Substance and Licensed Products Protalix anticipates requiring for supply outside of the Territory on a rolling four-calendar quarter basis, each of which shall update the prior projections (the "Protalix Projections"). On the Effective Date, or such later date that allows for delivery outside of the Territory, Protalix shall issue to Pfizer an initial forecast (the "Initial Protalix Forecast") for the four (4) calendar quarters commencing with the first quarter post approval of the Licensed Product for commercialization in Brazil, together with a firm purchase order for the first quarter for Licensed Product for delivery outside the Territory. The quantities of Licensed Product deliveries specified for the following quarter of the Initial Protalix Forecast shall be binding and the remaining two (2) quarters for the Initial Protalix Forecast shall be non-binding. Thereafter, ninety (90) days prior to the first business day of each subsequent calendar quarter, Protalix shall deliver to Pfizer a rolling four (4) calendar quarter forecast updating the prior forecast. The quantities of the Licensed Product deliveries for the following one (1) quarter shall be binding and the remaining two (2) quarters of such forecast shall be non-binding. Purchase orders for material outside the Territory will be issued in accordance with the Manufacturing Service and Supply Agreement between Pfizer Inc. [***] and Protalix."

13. Section 5.6 of the Agreement is hereby amended to add the following new Section 5.6(g): "The parties hereby agree to create and follow a monthly inventory accountability process, commencing in the month the Technical Transfer Agreement is executed, to provide both Protalix and Pfizer full transparency of global inventory positions of both Parties, movement of inventory between locations, consumption of inventory for technical trials, stability sampling, clinical programs and Commercialization both outside and inside the Territory, each as conducted by such Party."

14. Section 5.8 of the Agreement is hereby amended to add the following new Section 5.8(d): "Delivery Terms of Final Product or Packaged Product for Brazil. Notwithstanding anything in this Agreement to the contrary, any Licensed Product purchased by Protalix from Pfizer for purposes of Commercialization in Brazil, whether in fully-packaged form or in naked vials, shall be supplied to Protalix [***]. Such Licensed Product shall be shipped [***]. Protalix shall be responsible for [***] and for compliance with all applicable Laws and Regulatory Approvals for the Licensed Product in Brazil."

15. For the avoidance of doubt, until full completion of the Technology Transfer, as defined in the Technology Transfer Agreement, the Quality Agreement (including the change control procedures outlined in the Quality Agreement) shall apply to all proposed changes to the Drug Substance, Licensed Product manufacturing process and testing with respect to all territories including Brazil, with the intention of ensuring one common Drug Substance and Licensed Product process across territories and fungible inventory, as practical. Upon completion of the Technology Transfer, with respect to Brazil, Protalix shall reasonably consult with Pfizer regarding any proposed changes to the Drug Substance process with respect to Brazil, with the intention of ensuring one common Drug Substance process across territories and fungible inventory, such consultation as practical, but no less frequently than once per calendar year. Protalix shall use Commercially Reasonable Efforts to accommodate the suggestions of the Supply Chain Committee relating to any such proposed change, but shall retain sole discretion regarding whether any such proposed change shall be implemented with respect to Brazil, including implementation of any change that would create segregated specifications and inventories for Brazil.

16. Section 5.13 of the Agreement is hereby deleted in its entirety.

17. For purposes of this Letter Amendment and solely for purposes of establishing the accounting and procedure for payment in connection with the approval and commercialization of the Licensed Product in Brazil, (i) Section 7 of the Agreement is hereby amended to replace all references to "Pfizer" with "Protalix," all references to "Protalix" with "Pfizer", and all references to "the Territory" with "Brazil"; (ii) Section 7.1(a)(iii) will not apply; (iii) Section 7.1(b) is amended to delete the phrase (as revised) "Pfizer shall pay Pfizer's share of the Net Loss, if any, to Protalix"; and (iv) Sections 7.1(c) (i)-(iii), 7.1(d) and 7.6(a)-(c) will not apply. For all other purposes, Section 7 shall remain unchanged, except as set forth below.

18. For purposes of this Letter Amendment and solely for purposes of establishing the accounting and procedure for payment in connection with the approval and commercialization of the Licensed Product in Brazil, Section 7.1(c)(iv) is further amended to replace all references to “each party’s share of Net Profit” to “Pfizer’s share of Net Profit”. All references to “Net Loss” shall not apply.

19. For all purposes other than establishing the accounting and procedure for payment in connection with the approval and commercialization of the Licensed Product in Brazil, Section 7.1(c)(i) of the Agreement is hereby amended to change the amount [***] to [***].

20. Section 7.5 of the Agreement is hereby amended to add the following immediately after the reference to "calculation of Actual Price to be verified.": "Protalix shall, and shall cause its Affiliates and sublicensees to keep accurate books and records setting forth all payments and other transfers made by Protalix or any of its Affiliates or sublicensees in connection with the Technology Transfer Agreement."

21. For purposes of this Letter Amendment and the approval and commercialization of the Licensed Product in Brazil:

(a) Section 7.6 is hereby amended by adding the following, new Section 7.6(d): "VAT. It is understood and agreed between the Parties that any payments made by Protalix to Pfizer under this Agreement are exclusive of any value added or similar tax (VAT), which shall be added thereon as applicable.

(b) Section 7.6 is hereby amended by adding the following, new Section 7.6(e): "Tax Cooperation with respect to Brazil. To the extent Protalix is required to deduct and withhold taxes on any payments to Pfizer, Protalix shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Pfizer an official tax certificate or other evidence of such withholding sufficient to enable Pfizer to claim credits for such payments of taxes. Pfizer shall provide to Protalix any tax forms that may be reasonably necessary in order for Protalix not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Pfizer shall use reasonable efforts to provide any such tax forms to Protalix at least thirty (30) days prior to the due date for any payments for which Pfizer desires that Protalix apply a reduced withholding rate. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by law, of withholding taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax. Each party further agrees to provide reasonable cooperation to the other party, at the other party’s expense, in connection with any official or unofficial tax audit or contest relating to payments made by Protalix to Pfizer under this Agreement."

(c) Section 7.6 is hereby amended by adding the following, new Section 7.6(f): "Withholding Taxes with respect to Licensed Product Commercialized in Brazil. If Protalix is required to make a payment to Pfizer subject to a deduction of tax or withholding tax, (i) if such withholding or deduction obligation arises as a result of any failure on the part of Protalix to comply with applicable tax laws or filing or record retention requirements, that has the effect of modifying the tax treatment of the parties hereto (a "Protalix Withholding Tax Action"), then the sum payable by Protalix (in respect of which such deduction or withholding is required to be made) shall be increased to the extent necessary to ensure that Pfizer receives a sum equal to the sum which it would have received had no such Protalix Withholding Tax Action occurred, (ii) otherwise, the sum payable by Protalix (in respect of which such deduction or withholding is required to be made) shall be made to Pfizer after deduction of the amount required to be so deducted or withheld, which deducted or withheld amount shall be remitted to the applicable Governmental Authority in accordance with applicable Law."

(d) Notwithstanding anything to the contrary herein, (i) if Pfizer's invoicing to Protalix for the compensation due under this Letter Amendment (or Protalix's payment to Pfizer of any such amounts) or any other amounts required to be paid by Protalix to Pfizer in connection with the Letter Amendment or Technology Transfer Agreement (including the purchase of Licensed Product) would trigger the application of any value added or similar tax (VAT), Pfizer and Protalix shall negotiate in good faith to reach an agreement with respect thereto (including with respect to any reasonable and legally permissible arrangements to minimize or mitigate such taxes), with the intent of preserving the economics of the current arrangement between Protalix and Pfizer to the extent reasonably possible, and (ii) Pfizer shall not change the route of shipments of Licensed Products nor change the seller of the Licensed Products to a non-U.S. entity in any manner that would trigger the application of any such taxes for which Protalix is responsible hereunder absent agreement by the parties.

22. Section 9.4(b) of the Agreement is hereby amended to add the following immediately after the reference to "Except as set forth in Sections 9.3, 9.4(a) or 9.4(c)" therein:", or with respect to any activities or contemplated activities of Protalix relating to the Brazilian market".

23. Section 10.1(r) of the Agreement is hereby amended to (1) add the following immediately after the reference "Protalix": [***]

24. Section 10.1 of the Agreement is hereby amended by adding a new subsection (v): [***]

25. Section 10.1 of the Agreement is hereby amended by adding a new subsection (w): [***]

26. Section 10.1 of the Agreement is hereby amended by adding a new subsection (x): [***]

27. Section 10.1 of the Agreement is hereby amended by adding a new subsection (y): [***]

28. Section 10.1 of the Agreement is hereby amended by adding a new subsection (z): [***]

29. Appendix 10.1(t) is hereby deleted in its entirety and replaced with the attached new Appendix 10.1(t) hereto.

30. Exhibit I is hereby deleted in its entirety and replaced with attached new Exhibit I hereto.

31. Notwithstanding any other termination right Pfizer has in the Agreement, Pfizer may terminate this Letter Amendment (including the grant of rights to Protalix for Brazil contained herein and in relevant Sections of the Agreement (as amended hereby)) if Protalix breaches 10.1(v), (w), (y) or (z) of the Agreement (as amended hereby). In order to terminate pursuant to this paragraph with respect to any such breach, Pfizer must give written notice of termination to Protalix specifying such breach within fifteen (15) Business Days after Pfizer's termination right pursuant to this paragraph first arises with respect to such breach. Such termination shall be effective [***] after such written notice of termination is given, provided that such termination shall not be effective if (i) such breach has been cured within such [***] period, (ii) other than with respect to breach of Section 10.1 (z), within [***] of receiving such notice, [***].

32. Section 14.2(a) is hereby amended to add the following: "For the avoidance of doubt, and notwithstanding the foregoing, a breach of sections 10.1(r), (t), or (u) shall be considered a material breach for purposes of this section 14.2(a)."

33. Section 14.2(b) of the Agreement is hereby amended to add the following immediately after the reference to "applicable Laws are being or have been made": "or promised" and to add the following immediately after the reference to "to Government Officials by Protalix": "or any agent or subcontractor engaged in activities on behalf of Protalix" and to add the following immediately after the reference to "Protalix's provision of services to any Third Party": "or in connection with the Technology Transfer Agreement."

34. For purposes of this Letter Amendment and solely for the calculation of Net Profits and Net Loss in connection with the approval and commercialization of the Licensed Product in Brazil, Exhibit E of the Agreement shall be amended to: [***]

35. Protalix or its designee Fiocruz shall have the right to file a marketing authorization application in Brazil and seek Regulatory Approval for such application for the Licensed Product. In support of, and solely for use in connection with, the prosecution of such marketing authorization application and obtaining Regulatory Approvals for the Licensed Product in Brazil, Pfizer hereby grants to Protalix and its designee Fiocruz an exclusive right of access/reference in Brazil to any data, including clinical dossiers controlled by Pfizer or any of its Affiliates that relate to the Drug Substance or Licensed Product in Brazil, and Pfizer shall provide a signed statement to this effect, if requested by Protalix or its designee Fiocruz to the extent required in Brazil or otherwise provide appropriate notification of such right of Protalix or its designee Fiocruz to the applicable Regulatory Authority in Brazil. Pfizer shall (and shall cause its relevant Affiliates to) provide such assistance (including, without limitation, executing any documents or taking any actions reasonably requested by Protalix or its designee Fiocruz) as Protalix or its designee Fiocruz reasonably requires to obtain Regulatory Approvals (including, without limitation, filing marketing authorization applications) in its own name for the Licensed Product in Brazil (including cancellation of the corresponding marketing authorization held by Pfizer or Pfizer's Affiliate in Brazil if required by applicable Law or by an applicable Regulatory Authority in order for Protalix or its designee Fiocruz to obtain such Regulatory Approval). Protalix and its designee Fiocruz shall have the sole right to apply for and secure exclusivity rights that may be available under the Law of Brazil, including any Regulatory Exclusivity. Pfizer shall use Commercially Reasonable Efforts to cooperate with Protalix and its designee Fiocruz and to take such reasonable actions to assist Protalix and its designee Fiocruz, in obtaining such exclusivity rights in Brazil, as Protalix or its designee Fiocruz may reasonably request from time to time.

36. Until any marketing authorization application for Licensed Product submitted by Protalix or its designee Fiocruz is approved by the National Sanitary Surveillance Agency of the Brazilian Government (or any successor or replacement agency that has the authority to grant the necessary Regulatory Approvals) ("Anvisa") and any other required Regulatory Approval is obtained by Protalix or its designee Fiocruz, and with respect to any Pfizer or Pfizer Affiliate Regulatory Approvals and regulatory filings (including, without limitation, marketing authorizations) in Brazil and related data: (i) Pfizer shall provide Protalix notice of all meetings, conferences, and discussions (including meeting of experts convened by any Regulatory Authority in Brazil concerning any topic relevant to the Licensed Product) scheduled with any Regulatory Authority in Brazil concerning any regulatory matters relating to the Licensed Product promptly after the scheduling of such meeting, conference, or discussion (to the extent Pfizer is made aware of them in advance). Protalix or its designee Fiocruz shall be entitled to have one or more representatives present at all such meetings unless prohibited by Applicable Law or unless reasonably impracticable under the circumstances. Protalix or its designee Fiocruz and Pfizer shall use all reasonable efforts to agree in advance on the scheduling of such meetings, conferences and discussions and on the objectives to be accomplished at such meetings, conferences and discussions and the agenda for the meetings, conferences and discussions with such Regulatory Authority; provided that Pfizer shall have final decision-making authority over such matters, (ii) Pfizer shall provide Protalix or its designee Fiocruz with copies, which copies may be in draft form, of all material submissions to any Regulatory Authority in Brazil relating to the Licensed Product, to be provided sufficiently in advance of such planned submission to such Regulatory Authority in order to allow Protalix or its designee Fiocruz to provide comments regarding such submission, which comments shall be considered by Pfizer in good faith with respect to such submission; provided that Pfizer shall have final decision-making authority over such matters; (iii) Pfizer and Protalix (or Protalix's designee Fiocruz) shall provide to the other, as soon as reasonably practicable but in no event more than three (3) Business Days after its receipt, copies of any material documents or other material correspondence received from any Regulatory Authority in Brazil; and (iv) Pfizer shall reasonably cooperate with Protalix or its designee Fiocruz regarding (a) filings and communications with any Regulatory Authority, (b) patient advocacy and support, and (c) pharmacovigilance activities, in each case, in Brazil with respect to the Drug Substance or the Licensed Product; provided that Pfizer shall have final decision-making authority over such matters. For purposes of clarification, Pfizer is not obligated to pursue additional indications and/or submissions in Brazil other than required modifications due to those related to safety under the current, Pfizer marketing authorization.

37. Once Protalix or its designee Fiocruz has successfully received Regulatory Approval for the Licensed Product, Protalix shall have the sole authority and exclusive right to determine all regulatory plans and strategies for the Licensed Product in Brazil; provided that Protalix or its designee Fiocruz shall reasonably consider any comments on such plans and strategies that Pfizer may communicate through the Steering Committee or otherwise. Protalix (or one or more of its designated Affiliates) or its designee Fiocruz will own its marketing authorization application and be responsible for preparing, seeking, submitting and maintaining all related regulatory commitments including filings and Regulatory Approvals for the Licensed Product in Brazil, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval. Until Protalix or its designee Fiocruz have successfully received Regulatory Approval for the Licensed Product in Brazil (and the corresponding marketing authorization held by Pfizer or its Affiliate in Brazil has been cancelled), Protalix and its designee Fiocruz shall have express and irrevocable authorization and approval for Protalix and its designee Fiocruz to import the Licensed Product and Drug Substance into Brazil under Pfizer's or its Affiliates' Regulatory Approvals with Regulatory Authorities in Brazil, as allowed under applicable law, which express authorization and approval is set forth in writing on Exhibit E to this Letter Amendment (and which will be attached as an appendix to the Technology Transfer Agreement). Pfizer or Pfizer's relevant Affiliate shall issue one or more of such authorizations as reasonably required by Protalix or its designee Fiocruz.

38. Pfizer and Protalix shall negotiate in good faith to execute a Transitional Services Agreement ("TSA") for the Licensed Product within [***] of the effective date of this Letter Amendment, under which Pfizer will provide reasonable transitional services as needed, including those services set forth on Exhibit F. Within [***] of the execution of the Technology Transfer Agreement, and annually thereafter, Protalix and Pfizer shall mutually agree upon a written list of any services in addition to those set forth on Exhibit F to be performed under the TSA, which services are required to be performed under applicable Law. Protalix is liable to Pfizer for all actual Pfizer costs associated with providing such transitional services, as defined in the TSA and agreed upon by the Parties as set forth herein, from the date of the execution of this Letter Amendment, which costs shall not, in any event, exceed the costs set forth on Exhibit F, unless otherwise expressly agreed in advance by Protalix and Pfizer in writing. Notwithstanding the foregoing, Protalix shall be responsible for expenses relating to the engagement by Protalix of fully-dedicated medical personnel in Brazil to support the Licensed Product, as needed. Pfizer's obligation to provide Immediate Transitional Services (as identified in Exhibit F and to be defined in the TSA) shall terminate upon the earlier of (a) [***] following Protalix's or its designee Fiocruz's receipt of Regulatory Approval of the Licensed Product in Brazil or (b) with respect to a specific Immediate Transitional Service(s) or all Immediate Transitional Services, [***] upon written notice from Protalix. Pfizer agrees to provide Continued Transitional Services (as identified in Exhibit F and to be defined in the TSA) for at least [***] following the execution of the TSA, until mutually agreed upon by the parties; provided that Pfizer's obligation to provide Continued Transitional Services shall [***] following the execution of the TSA. Protalix may terminate specific or all Continued Transitional Services at any time [***] after the execution of the TSA, by providing [***] written notice to Pfizer. The TSA shall be appended hereto upon execution of such TSA as Exhibit G. Pfizer and Protalix shall negotiate in good faith to execute a revised pharmacovigilance agreement upon approval of Protalix or its designee Fiocruz's marketing authorization of the Licensed Product in Brazil. Such written plan shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit each Party to comply with applicable Laws, including any local regulatory requirements.

39. Pfizer acknowledges and agrees that, while this Letter Amendment is in effect, Protalix is permitted to sublicense to Fiocruz the Product Marks pursuant to the Technology Transfer Agreement for use as they exist on the labeling and packaging of finished packaged product at the time such finished packaged product is supplied to Fiocruz, and subject to the quality control provisions set forth in the Technology Transfer Agreement, which shall be at least as protective as those set forth in Section 4.9(d) of the Agreement.

40. Pfizer acknowledges and agrees that, while this Letter Amendment is in effect, Protalix is permitted to sublicense to Fiocruz any drug product manufacturing-related enhancements to or new presentations of Licensed Product developed or otherwise owned by Pfizer or its Affiliates ("Pfizer Improvements"), pursuant to the Technology Transfer Agreement, subject to the provisions set forth herein; provided that the Pfizer Improvements are used solely for the Licensed Product by Protalix and Fiocruz. In the event Protalix chooses to sublicense such Pfizer Improvements to Fiocruz, Pfizer shall provide reasonable technical support ("Technical Support") to transfer technical manufacturing information (all data in Pfizer's possession or control relating to process conditions, in-process controls, analytical methodology and formulation) relating solely to the Pfizer Improvement in connection with such sublicense to Protalix. Such Technical Support shall consist only of the transfer of the technical manufacturing information, as well as access to and availability of Pfizer personnel knowledgeable with respect to the Pfizer Improvement, including consultation by phone. Technical Support for each Pfizer Improvement will be limited to 40 person hours. Pfizer is not obligated to provide equipment, material, or additional people as part of Technical Support related to any Pfizer Improvement. Should additional Technical Support be required beyond the 40 person hours to complete the transfer of the technical manufacturing information ("Additional Technical Support"), Protalix shall provide to Pfizer a written request prior to initiation of such Additional Technical Support. Pfizer and Protalix must mutually agree on the Additional Technical Support. Protalix is liable to Pfizer for all actual Pfizer costs associated with Technical Support and Additional Technical Support to Protalix, including out-of pocket expenses (including, without limitation, reasonable travel, lodging and meal expenses) and costs of Pfizer's personnel, the latter to be charged to Protalix on a per-hour basis, at an hourly rate of [***].

41. Section 15.1 of the Agreement is hereby amended by (i) deleting the period at the end of subsection (a)(iii) thereof and replacing it with a semi-colon and (ii) adding the following new subsection (a)(iv): "(A) any claim made by an ATME Person against Pfizer for any consideration allegedly owed to an ATME Person in connection with Commercialization of the Licensed Product in Brazil, or the Technology Transfer Agreement, or (B) any inquiry, investigation, litigation or proceeding by a governmental authority or Third Party regarding any ATME Person in connection with the Commercialization of the Licensed Product in Brazil by Protalix, the Technology Transfer Agreement, or any other actions of an ATME Person on behalf of Protalix."

42. Pfizer and Protalix shall reasonably cooperate in good faith to execute any additional amendments or agreements, and take any other actions reasonably necessary to properly effectuate the terms and conditions of this Letter Amendment and to make the Agreement (and any related agreements) consistent with this Letter Amendment.

43. This Letter Amendment is not effective until the Technology Transfer Agreement in substantially the same form as of the date hereof has been signed by Protalix and Fiocruz and is in effect.

44. The terms and existence of this Letter Amendment (including the Exhibits hereto) and any negotiations between Pfizer and Protalix relating hereto shall be deemed the Confidential Information of both Pfizer and Protalix and shall be subject to the provisions of the Agreement relating to Confidential Information. Notwithstanding the foregoing, Pfizer acknowledges and agrees that Protalix BioTherapeutics, Inc. shall have the right to describe (and, as reasonably necessary, include) this Letter Amendment in its U.S. Securities and Exchange Commission ("SEC") filings; provided, that Pfizer and Protalix agree to reasonably cooperate with each other to prepare a redacted version of this Letter Amendment to be so filed with the SEC.

45. This Letter Amendment 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.

46. The terms of the Agreement shall remain in full force and effect, other than as set forth in this Letter Amendment or pursuant to the terms of the Agreement.

47. The provision of an unsigned draft of this Letter Amendment shall not be deemed an offer by, or create any obligation on behalf of, the party providing such draft. This Letter Amendment shall become effective only upon the execution of this Letter Amendment by both Pfizer and Protalix. This Letter Amendment may be executed in any counterparts, each of which, when executed, shall be deemed to be an original and which together shall constitute one and the same document.

Please indicate your agreement with the foregoing by countersigning a copy of this letter.

Very truly yours,

PROTALIX LTD.

By: /s/ David Aviezer
Name: David Aviezer, Ph.D.
Title: President and
Chief Executive Officer

Accepted and agreed this 18th day of June, 2013

PFIZER INC.

By: /s/ Diem Nguyen
Name: Diem Nguyen
Title: General Manager, Biosimilars

Exhibit A

[***]

Exhibit B

[***]

Exhibit C

[***]

Exhibit E

English-Language Version:

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., a limited liability company organized and existing under Brazilian law, with its principal place of business at Avenida Presidente Tancredo De Almeida Neves, 1555, in the City of Guarulhos, State of São Paulo, enrolled in the CNPJ under No. 46.070.868/0001-69, duly regularized before ANVISA – Agência Nacional de Vigilância Sanitária under Nº 1.00216-6, represented by its Legal Representative and Legal Responsible and by its Technical Responsible José Claudio Bumerad, CPF nº 057.594.678-40, CRF-SP nº 43.746, 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**
Product: Uplyso* (alfataliglicerase) Therapeutic class: Enzyme for replacement (*) Mark applied.	1.0216.0229.001-3	24 months

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 recognize the penalties to which we may be subject, pursuant to Law No. 6437, August 1977.

Legal Representative: _____

Legal Responsible:_____

Technical Responsible: José Claudio Bumerad – CPF nº 057.594.678-40/ CRF-SP nº 43.746

Valid for two years from issuance

Rio de Janeiro, _____.

_____ Legal Representative

_____ Legal Responsible

_____ Technical Responsible

Portuguese-Language Version:

À
Agência de Vigilância Sanitária (ANVISA/MS)

DECLARAÇÃO DE AUTORIZAÇÃO DE IMPORTAÇÃO
POR PESSOA JURÍDICA NÃO DETENTORA DA REGULARIZAÇÃO JUNTO À ANVISA
(Base legal: RDC Nº 81/08 – CAPÍTULO VII – ITEM 7B)

REFERENTE: Licença de Importação/LI nº _____/_____-_____

A empresa Laboratórios PFIZER Ltda., com uma sociedade limitada constituída e existente de acordo com as leis do Brasil, com sua sede social na Av. Presidente Tancredo de Almeida Neves, 1555 na Cidade de Guarulhos, Estado de São Paulo, inscrita no CNPJ sob nº. 46.070.868/0001-69, devidamente regularizada na ANVISA – Agência Nacional de Vigilância Sanitária sob o Nº 1.00216-6, representada pelo seu Representante Legal _____, Responsável Legal _____, e por seu Responsável Técnico José Claudio Bumerad, CPF nº 057.594.678-40, CRF-SP nº 43.746, abaixo assinados, concede Autorização para Importação, diretamente de sua fornecedora Protalix Ltd, do Produto abaixo indicado, do qual somos detentores do(s) documento(s) de regularização perante o Ministério da Saúde/Agência Nacional de Vigilância Sanitária.

Importador Autorizado:	Fiocruz – Instituto de Tecnologia em Imunobiológicos, Bio-Manguinhos CNPJ nº 33.781.055/0015-30

Descrição do produto para saúde:	**Nº de Registro ANVISA**	**Validade**
Produto: Uplyso* (alfataliglicerase) Classe terapêutica: Enzima para reposição (*) Marca depositada.	1.0216.0229.001-3	24 meses

Cumprindo a determinação da RDC nº 81/08, autorizamos única e exclusivamente o importador acima citado a utilizar e registro supracitado, sendo, portanto, verdade o repasse do mesmo.

Assumimos expressamente o compromisso de observância e cumprimento das normas e procedimentos pela legislação sanitária, bem como de ciência das penalidades as quais ficaremos sujeitos, nos termos da lei nº 6.437, de agosto de 1977.

Representante Legal: _____

Responsável Legal: _____

Responsável Técnico: José Claudio Bumerad – CPF nº 057.594.678-40/ CRF-SP nº 43.746

Válido por 2 anos da emissão

Rio de Janeiro, _____ de _____ de _____

_____ _____
Representante Legal do Responsável Legal Representante Legal

_____
Responsável Técnico

Exhibit F

SERVICES TO BE INCLUDED IN TRANSITIONAL SERVICES AGREEMENT

[***]

Exhibit G

TRANSITIONAL SERVICES AGREEMENT

[***]

Exhibit I

Pursuant to Section 10(u) of the Exclusive License and Supply Agreement between Pfizer Inc. ("Pfizer") and Protalix Ltd. ("Protalix") , dated as of November 30, 2009 and the amendment thereto dated [x],

I hereby certify:

[***]

PROTALIX LTD.

NAME: _____

TITLE: _____

DATE: _____

International Anti-Bribery and Anti-Corruption Principles

Pfizer has a longstanding corporate policy that prohibits colleagues or anyone acting on our behalf from providing any payment or benefit to any person or entity in order to improperly influence a government official or to gain an unfair business advantage. Pfizer is committed to performing with integrity, and acting ethically and legally in accordance with all applicable laws and regulations, including, but not limited to, anti-bribery and anti-corruption laws. We expect the same commitment from the consultants, agents, representatives or other companies and individuals acting on our behalf ("Business Associates"), as well as those acting on behalf of Business Associates, in connection with work for Pfizer.

Bribery of Government Officials

Most countries have laws that forbid making, offering or promising any payment or anything of value (directly or indirectly) to a government official when the payment is intended to influence an official act or decision to award or retain business. Under Pfizer's policies, "government official" is broadly interpreted 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, candidate for public office, officer, employee, or person acting for or on behalf of a political party or candidate for public office; or (iv) an employee or person acting for or on behalf of a public international organization (*e.g.*, the United Nations). "Government" is meant to include all levels and subdivisions of governments (*i.e.*, local, regional, or national and administrative, legislative, or executive). Because this definition of "government official" is so broad, it is likely that Business Associates will interact with a government official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by government-owned hospitals would be considered "government officials" under Pfizer's policies.

The U.S. Foreign Corrupt Practices Act of 1977 (the "FCPA") prohibits making, promising, or authorizing the making of a payment or providing anything of value to a non-U.S. government official to improperly or corruptly induce that official to make any governmental act or decision to assist a company in obtaining or retaining business, or to otherwise obtain an improper advantage. The FCPA also prohibits a company or person from using another company or individual to engage in any of the foregoing activities. As a U.S. company, Pfizer must comply with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Business Associate.

Appendix 10.1(t)

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Governments and Government Officials

Business Associates must communicate and abide by the following principles with regard to their interactions with governments and government officials:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any government official to induce that government official to make any governmental act or decision to help Pfizer obtain or retain business. Business Associates, and those acting on their behalf in connection with work for Pfizer, may never make a payment to or offer a government official any item or benefit, regardless of value, as an improper inducement for such government official to approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or otherwise improperly to benefit Pfizer's business activities.

- Business Associates, and those acting on their behalf in connection with work for Pfizer, need to understand whether local laws, regulations, or operating procedures (including requirements imposed by government entities such as government-owned hospitals or research institutions) impose any limits, restrictions, or disclosure requirements on compensation, financial support, donations, or gifts that may be provided to government officials. Business Associates, and those acting on their behalf in connection with work for Pfizer, must take into account and comply with any applicable restrictions in conducting their Pfizer-related activities. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions, or disclosure requirements with respect to interactions with government officials, that Business Associate should consult with his or her primary Pfizer contact before undertaking their activities.

- Business Associates, and those acting on their behalf in connection with work for Pfizer, are not permitted to offer facilitation payments. A "facilitation payment" is a nominal, unofficial payment to a government official for the purpose of securing or expediting the performance of a routine, non-discretionary governmental action. Examples of facilitation payments include payments to expedite the processing of licenses, permits or visas for which all paperwork is in order. In the event that a Business Associate, or someone acting on their behalf in connection with work for Pfizer, receives or becomes aware of a request or demand for a facilitation payment or bribe in connection with work for Pfizer, the Business Associate shall report such request or demand promptly to his or her primary Pfizer contact before taking any further action.

Commercial Bribery

Bribery and corruption can also occur in non-government, business to business relationships. Most countries have laws which prohibit offering, promising, giving, requesting, receiving, accepting, or agreeing to accept money or anything of value in exchange for an improper business advantage. Examples of prohibited conduct could include, but are not limited to, the provision of inappropriate gifts or hospitality, kickbacks, or investment opportunities offered to improperly induce the purchase of goods or services. Pfizer colleagues are not permitted to offer, give, solicit or accept bribes, and we expect our Business Associates, and those acting on their behalf in connection with work for Pfizer, to abide by the same principles.

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Private Parties and Pfizer Colleagues

Business Associates must communicate and abide by the following principles with regard to their interactions with private parties and Pfizer colleagues:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any person to induce that person to provide an unlawful business advantage for Pfizer.

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly, solicit, agree to accept, or receive a payment or anything of value as an improper inducement in connection with their business activities performed for Pfizer.

- Pfizer colleagues are not permitted to receive gifts, services, perks, entertainment, or other items of more than token or nominal monetary value from Business Associates, and those acting on their behalf in connection with work for Pfizer. Moreover, gifts of nominal value are only permitted if they are received on an infrequent basis and only at appropriate occasions.

[***] 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

1.1 For 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.

“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.

“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.

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)

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.

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.

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.

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).

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	[***]	[***]	[***]

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

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.

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.

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.

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.

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;

(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.

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)

[***]

APPENDIX II

TECHNOLOGY TRANSFER

[***]

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:

APPENDIX IV – PURCHASE ORDER

[***]

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

APPENDIX VI - LETTER OF CREDIT

[***]

APPENDIX VII

ACCOUNT INFORMATION

[***]

APPENDIX VIII
PHARMACOVIGILANCE AGREEMENT

[***]

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

[***]

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.

EXHIBIT 31.1

CERTIFICATION

I, David Aviezer, 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 8, 2014

/s/ David Aviezer
David Aviezer, Ph.D.
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Yossi Maimon, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 8, 2014

/s/ Yossi Maimon
Yossi Maimon
Chief Financial Officer, Treasurer

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, David Aviezer, 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 8, 2014

/s/ David Aviezer
David Aviezer, Ph.D.
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, 2014 as filed with the Securities and Exchange Commission (the "Report"), I, Yossi Maimon, Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

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

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

Date: May 8, 2014

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