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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2018

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

001-33357
(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

On November 1, 2018, approximately 148,374,921 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" and "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 caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and other statements included elsewhere in this Quarterly Report on Form 10-Q, which are not historical, constitute "forward-looking statements" within the meanings of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to the Company or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements.

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

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

- the risk that the results of our clinical trials will not support the applicable claims of superiority, safety or efficacy and that our product candidates will not have the desired effects or will have undesirable side effects or other unexpected characteristics;

- risks relating to our ability to manage our relationship with Chiesi Farmaceutici S.p.A., or Chiesi, and any other collaborator, distributor or partner;

- risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance or satisfy conversions of our outstanding convertible notes or any other indebtedness;

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

- our dependence on performance by third-party providers of services and supplies, including without limitation, clinical trial services;

- risks relating to our ability to finance our activities and research programs;

- delays in preparing and filing applications for regulatory approval of our product candidates in the United States, the European Union and elsewhere;

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

- the risk that products that are competitive to our product candidates may be granted orphan drug status in certain territories and, therefore, one or more of our product candidate may become be subject to potential marketing and commercialization restrictions;

- risks related to our supply of drug product to Pfizer Inc., or Pfizer, pursuant to our amended and restated exclusive license and supply agreement with Pfizer;
- risks related to the commercialization efforts for taliglucerase alfa in Brazil;
- risks related to our expectations with respect to the potential commercial value of our product and product candidates;
- the inherent risks and uncertainties in developing the types of drug platforms and products we are developing;
- potential product liability risks, and risks of securing adequate levels of product liability and clinical trial insurance coverage;
- the possibility of infringing a third-party's patents or other intellectual property rights;
- the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third-parties;
- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; and
- the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of regulatory authorities, our subsidiaries, our manufacturing facilities and our customers, suppliers, distributors, collaborative partners, licensees and clinical trial sites.

Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the 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 numerous risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These and other risks and uncertainties are detailed under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017, 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)

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,868	$ 51,163
Accounts receivable – Trade	4,894	1,721
Other assets	2,619	1,934
Inventories	7,959	7,833
Total current assets	$ 57,340	$ 62,651
DEFERRED ASSET	$ 1,450	
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,779	$ 1,887
PROPERTY AND EQUIPMENT, NET	6,628	7,676
Total assets	$ 67,197	$ 72,214
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,388	$ 7,521
Other	10,163	9,310
Convertible notes		5,921
Total current liabilities	$ 14,551	$ 22,752
LONG TERM LIABILITIES:		
Convertible notes	47,320	46,267
Deferred revenues	61,780	26,851
Liability for employee rights upon retirement	2,386	2,586
Other long term liabilities	6,154	5,051
Total long term liabilities	$ 117,640	$ 80,755
Total liabilities	$ 132,191	$ 103,507
COMMITMENTS		
CAPITAL DEFICIENCY	(64,994)	(31,293)
Total liabilities net of capital deficiency	$ 67,197	$ 72,214

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

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

	Nine Months Ended		Three Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
REVENUES	$ 7,222	$ 16,773	$ 663	$ 7,526
COST OF REVENUES	(7,024)	(13,677)	(1,917)	(6,066)
GROSS PROFIT (LOSS)	198	3,096	(1,254)	1,460
RESEARCH AND DEVELOPMENT EXPENSES (1)	(25,565)	(22,389)	(10,803)	(7,118)
LESS – GRANTS	1,810	2,545	732	729
RESEARCH AND DEVELOPMENT EXPENSES, NET	(23,755)	(19,844)	(10,071)	(6,389)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(7,294)	(8,187)	(2,638)	(2,836)
OPERATING LOSS	(30,851)	(24,935)	(13,963)	(7,765)
FINANCIAL EXPENSES	(5,824)	(8,809)	(1,811)	(3,680)
FINANCIAL INCOME	437	1,670	230	8
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE		(38,061)		
FINANCIAL EXPENSES, NET	(5,387)	(45,200)	(1,581)	(3,672)
NET LOSS FOR THE PERIOD	(36,238)	(70,135)	(15,544)	(11,437)
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED	$ (0.25)	$ (0.55)	$ (0.10)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	146,752,355	128,223,722	148,187,513	132,549,001
(1) Includes share-based compensation	$ 54	$ 163	$ 14	$ 43
(2) Includes share-based compensation	$ 42	$ 128	$ 8	$ 32

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

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

	Common Stock (1)	Common Stock	Additional Paid–In Capital	Accumulated Deficit	Total
	Number of shares	Amount			
Balance at December 31, 2016	**124,134,085**	**$ 124**	**$ 202,575**	**$ (212,656)**	**$ (9,957)**
Changes during the nine-month period ended September 30, 2017:					
Share-based compensation related to stock options			291		291
Reclassification of embedded derivative			43,634		43,634
Convertible notes conversions	9,711,235	10	8,771		8,781
Conversion component related to convertible notes issuance			1,315		1,315
Net loss for the period				(70,135)	(70,135)
Balance at September 30, 2017	**133,845,320**	**$ 134**	**$ 256,586**	**$ (282,791)**	**$ (26,071)**
Balance at December 31, 2017	**143,728,797**	**$ 144**	**$ 266,495**	**$ (297,932)**	**$ (31,293)**
Changes during the nine-month period ended September 30, 2018:					
Share-based compensation related to stock options			80		80
Share-based compensation related to restricted stock award	29,898	*	16		16
Convertible notes conversions	1,928,907	2	1,289		1,291
Convertible notes exchange	2,613,636	2	1,148		1,150
Net loss for the period				(36,238)	(36,238)
Balance at September 30, 2018	**148,301,238**	**$ 148**	**$ 269,028**	**$ (334,170)**	**$ (64,994)**

* Represents an amount less than $1.

(1) Common Stock, $0.001 par value; Authorized – as of September 30, 2018 and 2017 - 250,000,000.

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

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

	Nine Months Ended	
	September 30, 2018	**September 30, 2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (36,238)	$ (70,135)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share based compensation	96	291
Depreciation	1,257	1,469
Financial (income) expenses, net (mainly exchange differences)	(37)	13
Changes in accrued liability for employee rights upon retirement	(86)	54
Gain on amounts funded in respect of employee rights upon retirement	(45)	(21)
Net loss in connection with conversions of convertible notes	204	587
Change in fair value of convertible notes embedded derivative		38,061
Amortization of debt issuance costs and debt discount	1,916	1,710
Issuance of shares for interest payment in connection with conversions of convertible notes	205	1,111
Changes in operating assets and liabilities:		
Increase (decrease) in deferred revenues	34,929	(837)
Increase in deferred asset	(1,450)	
Increase in accounts receivable and other assets	(3,661)	(6,467)
Increase in inventories	(126)	(2,234)
Increase (decrease) in accounts payable and accruals	(1,805)	8,698
Increase in other long term liabilities	1,103	
Net cash used in continuing operations	(3,738)	(27,700)
Net cash provided by discontinued operations		116
Net cash used in operating activities	$ (3,738)	$ (27,584)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (498)	$ (681)
Increase in restricted deposit	(247)	(336)
Amounts funded in respect of employee rights upon retirement, net	70	(68)
Net cash used in investing activities	$ (675)	$ (1,085)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net payment for convertible notes	(4,752)	(10,961)
Net proceeds from issuance of convertible notes		9,542
Net cash used in financing activities	(4,752)	(1,419)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (130)	$ 289
NET DECREASE IN CASH AND CASH EQUIVALENTS	(9,295)	(29,799)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	51,163	63,281
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 41,868	$ 33,482

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

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

(Continued) - 2

	Nine Months Ended	
	September 30, 2018	**September 30, 2017**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 237	$ 666
Convertible notes conversions	$ 2,236	$ 7,668
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$ 2,411	$ 2,613

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the "Company"), and its wholly-owned subsidiaries, Protalix Ltd. and Protalix B.V. (the "Subsidiaries"), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company's proprietary ProCellEx® protein expression system ("ProCellEx"). To date, the Company has successfully developed taliglucerase alfa (marketed under the name alfataliglicerase in Brazil and certain other Latin American countries and Elelyso® in the rest of the territories) for the treatment of Gaucher disease that has been approved for marketing in the United States, Brazil, Israel and other markets. The Company has a number of product candidates in varying stages of the clinical development process. The Company's strategy is to develop proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications.

The Company's product pipeline currently includes, among other candidates:

(1) pegunigalsidase alfa, or PRX-102, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder;

(2) alidornase alfa, or PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or DNase, under development for the treatment of Cystic Fibrosis, to be administered by inhalation; and

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

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

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

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

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

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

Since its approval by the FDA, taliglucerase alfa has been marketed by Pfizer Inc. ("Pfizer"), in accordance with the exclusive license and supply agreement between Protalix Ltd. and Pfizer, which is referred to herein as the Pfizer Agreement. In October 2015, the Company entered into an Amended and Restated Exclusive License and Supply Agreement with Pfizer (the "Amended Pfizer Agreement") which amends and restates the Pfizer Agreement in its entirety. Pursuant to the Amended Pfizer Agreement, the Company sold to Pfizer its share in the collaboration created under the Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36.0 million. As part of the sale, the Company agreed to transfer its rights to Elelyso in Israel to Pfizer while gaining full rights to it in Brazil. Under the Amended Pfizer Agreement, Pfizer is entitled to all of the revenues, and is responsible for 100% of expenses globally for Elelyso, excluding Brazil where the Company is responsible for all expenses and retains all revenues.

On June 18, 2013, the Company entered into a Supply and Technology Transfer Agreement (the "Brazil Agreement") with Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health (the "Brazilian MoH"), for taliglucerase alfa. Fiocruz's purchases of alfataliglicerase to date have been significantly below certain agreed upon purchase milestones and, accordingly, the Company has the right to terminate the Brazil Agreement. Notwithstanding the termination right, the Company is, at this time, continuing to supply alfataliglicerase to Fiocruz under the Brazil Agreement, and patients continue to be treated with alfataliglicerase in Brazil. Approximately 10% of adult Gaucher patients in Brazil are currently treated with alfataliglicerase. The Company is discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, the Company will determine what it believes to be the course of action that is in the best interest of the Company.

In 2017, the Company received a purchase order from the Brazilian MoH for the purchase of alfataliglicerase for the treatment of Gaucher patients in Brazil for consideration of approximately $24.3 million. Shipments started in June 2017. The Company recorded revenues of $7.1 million for sales of alfataliglicerase to Fiocruz in 2017, and $2.6 million during the nine months ended September 30, 2018.

Based on its current cash resources and commitments, the Company believes it will be able to maintain its current planned development activities and the corresponding level of expenditures for at least 12 months from the date of approval of the September 30, 2018 financial statements, although no assurance can be given that it will not need additional funds prior to such time. If there are unexpected increases in general and administrative expenses or research and development expenses, the Company may need to seek additional financing.

b. Basis of presentation

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

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2017, filed by the Company with the Commission. The comparative balance sheet at December 31, 2017 has been derived from the audited financial statements at that date.

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

c. Net loss per share

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

Diluted LPS is calculated in continuing operations. The calculation of diluted LPS does not include 76,195,921 and 73,310,911 shares of Common Stock underlying outstanding options and restricted shares of Common Stock and shares of Common Stock issuable upon conversion of the convertible notes for the nine months ended September 30, 2017 and 2018, respectively, and 80,696,070 and 73,280,977 shares of Common Stock for the three months ended September 30, 2017 and 2018, respectively, because the effect would be anti-dilutive.

d. Revenue recognition

1. Revenues from supply agreements

   The Company recognizes revenues from supply agreements and from selling products when control is transferred to the customer and collectability is probable.

2. Revenues from Chiesi Agreements

   As Chiesi is obligated to acquire pegunigalsidase alfa from the Company and the development services are not considered distinct, development and manufacturing of a product to be commercialized by Chiesi is viewed as a single performance obligation under each of the agreements. Since there is only one performance obligation, all payments received from Chiesi prior to the satisfaction of the Company's obligation will be deferred. Therefore, the upfront payments and future research and development reimbursement payments and any potential additional development milestone payments under each agreement are contract liabilities and will be deferred until the commencement of commercial manufacturing in the applicable territories.

e. Recently adopted standards

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance on revenues from contracts with customers that will supersede most current revenue recognition guidance, including industry-specific guidance. The underlying principle is to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled to in exchange for those goods or services. The guidance provides a five-step analysis of transactions to determine when and how revenue is recognized. Other major provisions require capitalization of certain contracts costs, consideration of the time value of money in the transaction price, and allowing estimates of variable consideration to be recognized before contingencies are resolved in certain circumstances. The guidance also requires enhanced disclosures regarding the nature, amount timing and uncertainty of revenues and cash flows arising from an entity's contracts with customers. The guidance is effective for the interim and annual periods beginning on or after December 15, 2017. On January 1, 2018, the Company adopted the new accounting standard, ASC 606, Revenue from Contracts with Customers, and all the related amendments, using the modified retrospective method. The implementation of this Accounting Standards Update (ASU) did not have a material impact on the Company's consolidated financial statements.

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

In January 2016, the FASB issued ASU, No. 2016-01, Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities. The guidance affects the accounting for equity investments, financial liabilities under the fair value option and the presentation and disclosure requirements of financial instruments. The guidance is effective for annual reporting periods beginning after December 15, 2017. The implementation of this ASU did not have a material impact on the Company's consolidated financial statements.

NOTE 2 - INVENTORIES

The Company's inventory at September 30, 2018 and December 31, 2017 consisted of the following:

	September 30, 2018	December 31, 2017
	(U.S. dollars in thousands)	
Raw materials	$ 3,201	$ 3,838
Work in progress	276	485
Finished goods	4,482	3,510
Total inventory	$ 7,959	$ 7,833

NOTE 3 - FAIR VALUE MEASUREMENT

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

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

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

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

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

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

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

The fair value of the convertible notes derivative is based on Level 3 measurement.

The fair value of the remaining $58.0 million in aggregate principal amount of the Company's outstanding 7.50% secured convertible promissory notes due 2021 (the "2021 Notes") is approximately $78.0 million, based on a Level 3 measurement.

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

The Company prepared a valuation of the fair value of the Company's 2021 Notes (a Level 3 valuation) as of September 30, 2018. The value of these notes was estimated by implementing the binomial model. The liability component was valued based on the Income Approach. The following parameters were used:

	2021 Notes
Stock price (USD)	0.73
Expected term (years)	3.13
Risk free rate	2.87%
Volatility	75.56%
Yield	13.50%

NOTE 4 - CONVERTIBLE NOTES

All of our outstanding convertible notes are accounted for using the guidance set forth in the FASB Accounting Standards Codification (ASC) 815 which requires that the Company determine whether the embedded conversion option must be separated and accounted for separately. ASC 470-20, regarding debt with conversion and other options, requires the issuer of a convertible debt instrument that may be settled in cash upon conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer's nonconvertible debt borrowing rate.

The 2021 Notes were accounted for partially as liability and equity components of the instrument and partially as a debt host contract with an embedded derivative resulting from the conversion feature. During the year ended December 31, 2017, the embedded derivative was reclassified to additional paid in capital.

Issuance costs regarding the issuance of the 2021 Notes are amortized using the effective interest rate.

During the nine months ended September 30, 2018, note holders converted $1.1 million aggregate principal amount of the 2021 Notes into a total of 1,456,354 shares of Common Stock, and cash payments of approximately $14,439, in the aggregate. An additional 14,860 shares of Common Stock were issued after September 30, 2018 in connection with the make-whole premium associated with certain of the converted notes that were converted during the third quarter of 2018. In addition, in June 2018, the Company exchanged $3.42 million aggregate principal amount of the Company's outstanding 4.50% convertible promissory notes due 2018 (the "2018 Notes") for 2,613,636 shares of Common Stock and approximately $2.2 million in cash and delivered the necessary funds under the indenture governing the 2018 Notes, which was $2.5 million. On September 15, 2018, the 2018 Notes matured and have been paid in full.

As of September 30, 2018, a total of $58.0 million aggregate principal amount of the 2021 Notes were outstanding. In addition, as of September 30, 2018, none of the 2018 Notes were outstanding.

NOTE 5 - REVENUES

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

	Nine Months Ended September 30,	
(U.S. dollars in thousands)	**2018**	**2017**
Revenues:		
Pfizer	$ 4,649	$ 10,198
Brazil	$ 2,573	$ 6,575
	$ 7,222	**$ 16,773**

NOTE 6 - STOCK TRANSACTIONS

On September 13, 2018, the Company's compensation committee approved the grant of 10-year options to purchase, in the aggregate, 6,360,000 shares of Common Stock, of which options to purchase 4,000,000 shares of Common Stock were granted to the Company's executive officers and options to purchase 2,360,000 shares of Common Stock were granted to other employees with an exercise price equal to $0.56 per share and $0.51 per share, respectively, under the Company's 2006 Employee Stock Incentive Plan, as amended (the "Plan"). The options vest over a four-year period in 16 equal quarterly increments. Vesting of the options granted to the executive officers is subject to acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan, and are subject to certain other terms and conditions. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $1.9 million based on the following weighted average assumptions: share price equal to $0.51; dividend yield of 0% for all years; expected volatility of 64.3%; risk-free interest rates of 2.9%; and expected life of six years.

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, 2017. 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, 2017 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins based on our proprietary ProCellEx® protein expression system. We developed our first commercial drug product, Elelyso®, using our ProCellEx system and we are now focused on utilizing the system to develop a pipeline of proprietary, clinically superior versions of recombinant therapeutic proteins that primarily target large, established pharmaceutical markets and that in most cases rely upon known biological mechanisms of action. With our experience to date, we believe ProCellEx will enable us to develop additional proprietary recombinant proteins that are therapeutically superior to existing recombinant proteins currently marketed for the same indications including applying the unique properties of our ProCellEx system for the oral delivery of therapeutic proteins.

On October 19, 2017, Protalix Ltd., our wholly-owned subsidiary, and Chiesi entered into the Chiesi Agreement pursuant to which Chiesi was granted an exclusive license for all markets outside of the United States to commercialize pegunigalsidase alfa. Pegunigalsidase alfa is our chemically modified version of the recombinant protein alpha-Galactosidase-A protein that is currently being evaluated in phase III clinical trials for the treatment of Fabry disease. Under the terms and conditions of the Chiesi Agreement, Protalix Ltd. retained the right to commercialize pegunigalsidase alfa in the United States. Under the Chiesi Agreement, Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of the agreement and Protalix Ltd. is entitled to additional payments of up to $25.0 million in development costs, capped at $10.0 million per year. Protalix Ltd. is also eligible to receive an additional up to $320.0 million, in the aggregate, in regulatory and commercial milestone payments. Protalix Ltd. agreed to manufacture all of the PRX-102 needed for all purposes under the agreement, subject to certain exceptions, and Chiesi will purchase pegunigalsidase alfa from Protalix, subject to certain terms and conditions. Chiesi is required to make tiered payments of 15% to 35% of its net sales, depending on the amount of annual sales, as consideration for the supply of pegunigalsidase alfa.

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

In December 2017, the European Commission granted Orphan Drug Designation for pegunigalsidase alfa for the treatment of Fabry disease. The designation was granted after the European Medicine Agency's Committee for Orphan Medicinal Products, or the COMP, issued a positive opinion supporting the designation noting that we had established that there was medically plausible evidence that pegunigalsidase alfa will provide a significant benefit over existing approved therapies in the European Union for the treatment of Fabry disease. The COMP cited clinical and non-clinical justifications we provided to establish the significant benefit of pegunigalsidase alfa, noting that the COMP considered the justifications to constitute a clinically relevant advantage. Orphan Drug Designation for pegunigalsidase alfa qualifies Protalix Ltd. for access to a centralized marketing authorization procedure, including applications for inspections and for protocol assistance. If the orphan drug designation is maintained at the time pegunigalsidase alfa is approved for marketing in the European Union, if at all, we expect that PRX-102 will benefit from 10 years of market exclusivity within the European Union. The market exclusivity will not have any effect on Fabry disease treatments already approved at that time.

In January 2018, the FDA granted Fast Track designation to PRX-102. Fast Track designation is a process designed to facilitate the development and expedite the review of drugs and vaccines for serious conditions that fill an unmet medical need.

On May 1, 2012, the FDA approved for sale our first commercial product, taliglucerase alfa for injection, an ERT for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. Subsequently, taliglucerase alfa was approved for marketing by the regulatory authorities of other countries. Taliglucerase alfa is marketed under the name alfataliglicerase in Brazil and certain other Latin American countries, and under the name Elelyso in other territories.

Since its approval by the FDA, taliglucerase alfa has been marketed by Pfizer, as provided in the Pfizer Agreement. In October 2015, we entered into the Amended Pfizer Agreement which amends and restates the Pfizer Agreement in its entirety. Pursuant to the Amended Pfizer Agreement, we sold to Pfizer our share in the collaboration created under the initial Pfizer Agreement for the commercialization of Elelyso in exchange for a cash payment equal to $36.0 million. As part of the sale, we agreed to transfer our rights to Elelyso in Israel to Pfizer, while gaining full rights to Elelyso in Brazil. We will continue to manufacture drug substance for Pfizer, subject to certain terms and conditions. Under the Amended Pfizer Agreement, Pfizer is responsible for 100% of expenses, and entitled to all revenues globally for Elelyso, excluding Brazil, where we are responsible for all expenses and retain all revenues.

For the first 10-year period after the execution of the Amended Pfizer Agreement, we have agreed to sell drug substance to Pfizer for the production of Elelyso, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods subject to certain terms and conditions. Any failure to comply with our supply commitments may subject us to substantial financial penalties, which will have a material adverse effect on our business, results of operations and financial condition. The Amended Pfizer Agreement also includes customary provisions regarding cooperation for regulatory matters, patent enforcement, termination, indemnification and insurance requirements.

On June 18, 2013, we entered into the Brazil Agreement with Fiocruz, an arm of the Brazilian MoH, for taliglucerase alfa. Fiocruz's purchases of alfataliglicerase to date have been significantly below certain agreed upon purchase milestones and, accordingly, we have the right to terminate the Brazil Agreement. Notwithstanding our termination right, we are, at this time, continuing to supply alfataliglicerase to Fiocruz under the Brazil Agreement, and patients continue to be treated with alfataliglicerase in Brazil. We are discussing with Fiocruz potential actions that Fiocruz may take to comply with its purchase obligations and, based on such discussions, we will determine what we believe to be the course of action that is in our best interest.

We are developing an innovative product pipeline using our ProCellEx protein expression system. Our product pipeline currently includes, among other candidates:

(1) pegunigalsidase alfa, or PRX-102, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder in humans, currently in an ongoing phase III clinical trial.

(2) alidornase alfa, or PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1 under development for the treatment of Cystic Fibrosis, or CF, to be administered by inhalation. We recently completed a phase IIa efficacy and safety study of alidornase alfa for the treatment of CF.

(3) OPRX-106, our oral antiTNF product candidate which is being developed as an orally-delivered anti-inflammatory treatment using plant cells as a natural capsule for the expressed protein. We released final data generated in our phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis in March 2018. Additional data was released in June 2018.

We have licensed the rights to commercialize taliglucerase alfa worldwide (other than Brazil) to Pfizer, and the rights to commercialize pegunigalsidase alfa worldwide to Chiesi. Otherwise, we hold the worldwide commercialization rights to our other proprietary development candidates. In addition, we continuously evaluate potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutes.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing in this Quarterly Report. There have been no material changes to our significant accounting policies since we filed our Annual Report on Form 10-K for the year ended December 31, 2017.

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.

Convertible Notes

Our 2021 Notes are accounted for using the guidance set forth in FASB ASC 815 which requires that we determine whether the embedded conversion option must be separated and accounted for separately. ASC 470-20, regarding debt with conversion and other options, requires the issuer of a convertible debt instrument that may be settled in cash upon conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer’s nonconvertible debt borrowing rate.

Our 2021 Notes were accounted for partially as liability and equity components of the instrument and partially as a debt host contract with an embedded derivative resulting from the conversion feature. During the year ended December 31, 2017, the embedded derivative was reclassified to additional paid in capital.

Issuance costs regarding the issuance of the 2021 Notes are amortized using the effective interest rate.

During the nine months ended September 30, 2018, note holders converted $1.1 million aggregate principal amount of the 2021 Notes into a total of 1,456,354 shares of our common stock, and cash payments of approximately $14,439, in the aggregate. An additional 14,860 shares of common stock were issued after September 30, 2018 in connection with the make-whole premium associated with certain of the converted notes that were converted during the third quarter of 2018. On September 15, 2018, our 2018 Notes matured and the outstanding principal amount for such notes was paid in full.

As of September 30, 2018, a total of $58.0 million aggregate principal amount of the 2021 Notes were outstanding, and no 2018 Notes were outstanding.

Results of Operations

Three months ended September 30, 2018 compared to the three months ended September 30, 2017

Revenues

We recorded revenues of $663,000 during the three months ended September 30, 2018, a decrease of $6.9 million from revenues of $7.5 million for the three months ended September 30, 2017. The decrease resulted from decreased sales of drug substance to Pfizer and drug product to Brazil.

Cost of Revenues

Cost of revenues was $1.9 million for the three months ended September 30, 2018, a decrease of $4.1 million, from cost of revenues of $6.1 million for the three months ended September 30, 2017. The decrease resulted primarily from decreased sales of drug substance to Pfizer and drug product to Brazil.

Research and Development Expenses, Net

Research and development expenses were $10.1 million for the three months ended September 30, 2018, an increase of $3.6 million from $6.4 million for the three months ended September 30, 2017. The increase resulted primarily from an increase in clinical trial activity during 2018.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.6 million for the three months ended September 30, 2018, a decrease of $198,000, or 7%, from $2.8 million for the three months ended September 30, 2017. The decrease resulted primarily from a decrease in sales expenses.

Financial Expenses, net

Financial expenses, net were $1.6 million for the three months ended September 30, 2018, a decrease of $2.1 million compared to financial expenses, net of $3.7 million for the three months ended September 30, 2017. Financial expenses are comprised primarily from interest expense on our outstanding convertible notes of $1.2 million for the period ended September 30, 2018.

Nine months ended September 30, 2018 compared to the nine months ended September 30, 2017

Revenues

We recorded revenues of $7.2 million during the nine months ended September 30, 2018, a decrease of $9.6 million, or 57%, from revenues of $16.8 million for the nine months ended September 30, 2017. The decrease resulted from a decrease of $5.6 million in sales of drug substance to Pfizer and $4.0 million in sales of drug product to Brazil.

Cost of Revenues

Cost of revenues was $7.0 million for the nine months ended September 30, 2018, a decrease of $6.7 million, or 49%, from cost of revenues of $13.7 million for the nine months ended September 30, 2017. The decrease resulted primarily from costs related to the production of drug substance sold to Pfizer and drug product sold to Brazil.

Research and Development Expenses, Net

Research and development expenses was $23.8 million for the nine months ended September 30, 2018, an increase of $4.0 million, or 20%, from $19.8 million for the nine months ended September 30, 2017. The increase resulted primarily from an increase in clinical trial activity during 2018.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $7.3 million for the nine months ended September 30, 2018, a decrease of $893,000, or 11%, from $8.2 million for the nine months ended September 30, 2017. The decrease resulted primarily from a decrease in sales expenses.

Financial Expenses, net

Financial expenses, net were $5.4 million for the nine months ended September 30, 2018, compared to financial expenses net of $45.2 million for the nine months ended September 30, 2017. During the nine months ended September 30, 2017, financial expenses included a charge of $38.1 million as a result of the re-measurement of the fair value of the 7.5% convertible notes embedded derivative. In addition, financial expenses are comprised primarily from interest expense on our outstanding convertible notes.

Liquidity and Capital Resources

Sources of Liquidity

As a result of our significant research and development expenditures and the lack of significant revenue from sales of taliglucerase alfa, we have incurred operating losses from our continuing operations since our inception. 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 $50.0 million in connection with an underwritten public offering of our common stock and on each of March 23, 2011 and February 22, 2012, we generated gross proceeds of $22.0 million and $27.2 million, respectively, in connection with underwritten public offerings of our common stock.

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, including $9.0 million aggregate principal amount of the of 4.50% convertible notes related to the offering's initial purchaser's over-allotment option, which was exercised in full. In December 2016, we completed a private placement of $22.5 million in aggregate principal amount of 7.50% convertible notes due 2021. Finally, on July 25, 2017, we completed a private placement of an additional $10.0 million in aggregate principal amount of 7.50% convertible notes due 2021.

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 milestone. Protalix Ltd. also received a milestone payment of $25.0 million in connection with the FDA's approval of taliglucerase alfa in May 2012. Pfizer has also paid Protalix Ltd. $8.3 million in connection with the successful achievement of milestones under a clinical development agreement between Pfizer and Protalix Ltd. In connection with the execution of the Amended Pfizer Agreement, we received a $36.0 million payment from Pfizer, and Pfizer purchased 5,649,079 shares of our common stock for $10.0 million.

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

Cash Flows

Net cash used in operations was $3.7 million for the nine months ended September 30, 2018. The net loss for the nine months ended September 30, 2018 of $36.2 million was partially offset by an increase of $34.9 million in deferred revenues representing an upfront payment and certain expense reimbursements actually received from Chiesi in connection with our license agreements with Chiesi which, according to revenue recognition rules, were deferred and not recognized during the period in which the payments were received. Net cash used in investing activities for the nine months ended September 30, 2018 was $675,000 and consisted primarily of purchases of property and equipment, and an increase in restricted deposit. Net cash used in financing activities was $4.8 million for the repayment of convertible notes.

Net cash used in operations was $27.6 million for the nine months ended September 30, 2017. The net loss for the nine months ended September 30, 2017 of $70.1 million was partially offset by a change of $38.1 million in the fair value of convertible notes embedded derivative and increase of $8.7 million in accounts payable. Net cash used in investing activities for the nine months ended September 30, 2017 was $1.1 million and consisted primarily of purchases of property and equipment and an increase in restricted deposit. Net cash used in financing activities for the nine months ended September 30, 2017 was $1.4 million and consisted primarily of cash settlement of $11.0 million for certain conversions of our convertible notes which was partially offset by $9.5 million of net proceeds from the issuance of our 2021 Notes.

Future Funding Requirements

We expect to continue to incur significant expenditures in the near future, including significant research and development expenses related primarily to the clinical trials of pegunigalsidase alfa. We believe that our existing cash and cash equivalents and commitments will be sufficient for at least 12 months. We have based this estimate on assumptions that are subject to change and may prove to be wrong, and we may be required to use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical trials.

Our future capital requirements will depend on many other factors, including our progress in commercializing alfataliglicerase in Brazil, the progress and results of our clinical trials, particularly our clinical trials of pegunigalsidase alfa, the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates, conversions of our outstanding 2021 Notes from time to time, the timing and outcome of regulatory review of our product candidates, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, the number and development requirements of other product candidates that we pursue and the costs of commercialization activities, including product marketing, sales and distribution.

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

Effects of Inflation and Currency Fluctuations

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations during the nine months ended September 30, 2018 and September 30, 2017.

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services. We do not believe currency fluctuations have had a material effect on our results of operations during the nine months ended September 30, 2018 and September 30, 2017.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2018 and September 30, 2017.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Currency Exchange Risk

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

A portion of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A devaluation of 1% of the NIS will affect our income before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Nine months ended September 30,		Year ended December 31,
	2018	2017	2017
Average rate for period	3.558	3.629	3.600
Rate at period end	3.627	3.529	3.467

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 control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended September 30, 2018 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

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 nine months ended September 30, 2018.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File Number	Exhibit	Date	Filed or Furnished Herewith
3.1	Certificate of Incorporation of the Company	8-K	333-48677	3.1	April 1, 2016	
3.2	Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	July 1, 2016	
3.4	Bylaws of the Company	8-K	001-33357	3.2	April 1, 2016	
4.1	Form of Restricted Stock Agreement/Notice	8-K	001-33357	4.1	July 18, 2012	
4.2	Indenture, dated as of September 18, 2013, between Protalix BioTherapeutics, Inc. and The Bank of New York Mellon Trust Company, N.A., as Trustee	8-K	001-33357	4.1	September 18, 2013	
4.3	Form of 4.50% Convertible Note due 2018	8-K	001-33357	4.2	September 18, 2013	
4.4	Indenture, dated as of December 7, 2016, between Protalix BioTherapeutics, Inc. the guarantors party thereto, The Bank of New York Mellon Trust Company, N.A., as trustee and Wilmington Savings Fund Society, FSB, as collateral agent	8-K	001-33357	4.1	December 7, 2016	

4.5	Form of 7.50% Convertible Note due 2021 (Issued in 2016 Financing)	8-K	001-33357	4.2	December 7, 2016	
4.6	Form of 7.50% Convertible Note due 2021 (Issued in 2016 Exchange)	8-K	001-33357	4.3	December 7, 2016	
4.7	First Supplemental Indenture, dated as of July 24, 2017, by and among Protalix BioTherapeutics, Inc., the guarantors party thereto, The Bank of New York Mellon Trust Company, N.A., as trustee, and Wilmington Savings Fund Society, FSB, as collateral agent	8-K	001-33357	4.2	July 25, 2017	
4.8	Second Supplemental Indenture, dated as of November 27, 2017, by and among Protalix BioTherapeutics, Inc., the guarantors party hereto and The Bank of New York Mellon Trust Company, N.A., as trustee, registrar, paying agent and conversion agent	8-K	001-33357	4.1	December 1, 2017	
10.1†	Exclusive U.S. License and Supply Agreement dated as of July 23, 2018, made by and between Protalix Ltd. and Chiesi Farmaceutici S.p.A.					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer					X
32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer					X

101.INS	XBRL INSTANCE 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

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

SIGNATURES

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

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: November 7, 2018 By: /s/ Moshe Manor
Moshe Manor
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2018 By: /s/ Yossi Maimon
Yossi Maimon
Vice President and Chief Financial Officer,
Treasurer and Secretary
(Principal Financial and Accounting Officer)

Exhibit 10.1

EXECUTION VERSION

Portions of this exhibit have been omitted pursuant to a request for confidential treatment pursuant to 17 C.F.R. Sections 200.80(b)(4) and 240.24b-2(b). The omitted portions, marked by [***], have been separately filed with the Securities and Exchange Commission.

EXCLUSIVE U.S. LICENSE AND SUPPLY AGREEMENT

by and between

CHIESI FARMACEUTICI S.p.A.

and

PROTALIX LTD.

JULY 23, 2018

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

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

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Exhibit C – Press Release
Exhibit D – Chiesi Anti-Bribery Policy
Exhibit E – Chiesi Code of Ethics and Conduct

EXCLUSIVE U.S. LICENSE AND SUPPLY AGREEMENT

This Exclusive U.S. License and Supply Agreement (this "Agreement") dated as of the 23rd day of July, 2018 is made 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. Box 455, Carmiel 20100, Israel ("Protalix"), and Chiesi Farmaceutici S.p.A., a company incorporated under the laws of Italy with offices located at Largo F. Belloli, 11/A, 43122 Parma, Italy ("Chiesi") (each, a "Party" and collectively, 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 Fabry Disease;

WHEREAS, Chiesi has extensive experience and expertise in the development and commercialization of drug products;

WHEREAS, Protalix and Chiesi are parties to that certain Exclusive License and Supply Agreement dated October 17, 2017, pursuant to which Protalix granted to Chiesi an exclusive license outside the Territory (as defined below) to such patents, patent applications, technology, know-how and scientific and technical information, upon the terms and subject to the conditions set forth therein (such agreement, the "Ex-US Agreement");

WHEREAS, Chiesi now desires to acquire an exclusive license in the Territory to such patents, patent applications, technology, know-how and scientific and technical information, upon the terms and subject to the conditions set forth herein; and

WHEREAS, Protalix desires to grant such license to Chiesi.

NOW, THEREFORE, in consideration of the mutual covenants and agreements provided herein, Protalix and Chiesi hereby agree as follows:

Section 1. DEFINITIONS

For purposes of this Agreement, the following definitions shall be applicable:

1.1 "Acquisition" means, with respect to Protalix Parent (i) a completed Business Combination Transaction, unless, immediately following such completed Business Combination Transaction all or substantially all of the individuals and entities who were the beneficial owners of the outstanding voting securities of Protalix Parent immediately prior to such completed Business Combination Transaction beneficially own, directly or indirectly (including through one more holding companies or subsidiaries) at least fifty percent (50%) of the then-outstanding voting securities entitled to vote generally in the election of directors of the corporation or other entity resulting from such completed Business Combination Transaction (including a corporation or other entity that as a result of such transaction owns Protalix Parent or all or substantially all of a Protalix Parent's assets either directly or through one or more subsidiaries); (ii) the acquisition, directly or indirectly, by any Person (other than Chiesi or its Affiliates) of beneficial ownership of at least fifty percent (50%) or more of the outstanding voting securities of Protalix Parent, or (iii) the acquisition by a Third Party of all or substantially all of the assets of Protalix or Protalix Parent. As used in this Agreement, "voting securities" means any securities of Protalix Parent entitled to vote on the election of directors.

1.2 "Additional Studies" means [***].

1.3 "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, "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 fifty-percent (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 definition of Protalix Patent Rights and the definition of Protalix Technology, and with respect to the grant of license rights by Protalix to Chiesi under Section 2 in respect of such Protalix Patent Rights and Protalix Technology, "Affiliates" of Protalix shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of Protalix.

1.4 "Alliance Manager" shall have the meaning assigned to it in Section 3.3(a).

1.5 "Annual Cap" shall have the meaning assigned to it in Section 5.3(d).

1.6 "Annual Net Sales" means Net Sales for any Commercial Year.

1.7 "Applicable Rate" shall have the meaning assigned to it in Section 4.6(f).

1.8 "Audit" shall have the meaning assigned to it in Section 6.6.

1.9 "Average Sales Price" shall have the meaning assigned to it in Section 4.6(e).

1.10 [***]

1.11 [***]

1.12 [***]

1.13 [***]

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

1.14 "Business Combination Transaction" means any tender or exchange offer to Protalix Parent's stockholders, or any other offer or proposal to Protalix Parent or its stockholders for any merger, consolidation, restructuring, recapitalization or similar transaction with or involving Protalix Parent.

1.15 "Business Day" means a day other than a Saturday, Sunday, or bank or other public holiday in New York, New York, Parma, Italy or Carmiel, Israel.

1.16 "Buy-Back Payment" shall have the meaning assigned to it in Section 12.1(d).

1.17 "Calendar Quarter" means each of the four (4) three (3) month periods commencing on January 1 of any Calendar Year and ending on (respectively) March 31, June 30, September 30, and December 31 of such Calendar Year.

1.18 "Calendar Year" means the twelve (12) month period commencing on January 1 and ending on December 31 of any calendar year; provided that the first Calendar Year of the Term, shall commence on the Effective Date and end on December 31 of such calendar year and the last Calendar Year of the Term shall end on the date of expiration or termination of this Agreement.

1.19 "Claims" shall have the meaning assigned to it in Section 13.1.

1.20 "Clinical Data" means all clinical data (including, for the avoidance of doubt, all statistics, statistical source data, and associated required formatting) generated by or on behalf of either Party in the course of performance of any clinical studies conducted in respect of the Licensed Product in the Field.

1.21 "Change of Control" means the occurrence of any of the following: (a) any consolidation or merger of a Party with or into any Third Party, or any other corporate reorganization involving a Third Party, in which those persons or entities that are stockholders of such Party immediately prior to such consolidation, merger or reorganization own less than fifty percent (50%) of the surviving entity's voting power immediately after such consolidation, merger or reorganization; (b) a change in the legal or beneficial ownership of fifty percent (50%) or more of the voting securities of any Party (whether in a single transaction or series of related transactions) where, immediately after giving effect to such change, the legal or beneficial owner of more than fifty percent (50%) of the voting securities of such Party is a Third Party; or (c) the sale, transfer, lease, license or other disposition of all or substantially all of a Party's assets related to this Agreement in one or a series of related transactions to a Third Party.

1.22 "Chiesi Chair" means one of the Chiesi representatives on the Steering Committee designated by Chiesi as Chiesi's chair for Steering Committee Meetings.

1.23 "Chiesi Confidential Information" means all information or data of a proprietary or confidential nature relating to the Commercialization of the Licensed Product in the Field in the Territory, as well as any other information regarding the business, operations, Technology and Commercialization activities of Chiesi, whether in oral, written, graphic, machine-readable form, or any other form, (provided that data and information disclosed orally or visually are confirmed in writing by Chiesi within thirty (30) days after the date of such disclosure), disclosed and/or made available by or on behalf of Chiesi to Protalix, Protalix's Affiliates, and its and their respective directors, officers, employees, consultants, contractors and agents or otherwise acquired by any such Persons as a result of or in connection with this Agreement and/or the Parties' discussions (whether prior to the execution hereof or thereafter). Notwithstanding the foregoing, unmarked information and un-confirmed information will be considered Chiesi Confidential Information under this Agreement if a reasonable person familiar with the Licensed Product and given the nature of information and the circumstances of disclosure would consider such information to be confidential. Such information shall not be considered to be Chiesi Confidential Information to the extent that such information is: (a) as of the date of disclosure known to Protalix or its Affiliates, as demonstrable in any tangible medium in existence at the time of disclosure; or (b) wholly disclosed in published literature, or otherwise is or becomes generally known to the public through no breach by Protalix of this Agreement; or (c) obtained by Protalix or its Affiliates from a Third Party free from any obligation of confidentiality to Chiesi; or (d) independently developed by Protalix or its Affiliates without use of or reference to the Chiesi Confidential Information.

1.24 "Commercial Medical Affairs and Pharmacovigilance" has the meaning assigned to it in Section 3.6(d)(iv).

1.25 "Commercial Quarter" means each of the four (4) consecutive three (3) month periods of each Commercial Year, with the first Commercial Quarter commencing on first day of such Commercial Year (other than the first Commercial Quarter of the first Commercial Year, which shall commence on the first day of such Commercial Year, but end on the last day of the subsequent Calendar Quarter, i.e., including the period from Launch through the end of the subsequent full Calendar Quarter) and the last Commercial Quarter ending on the last day of such Commercial Year.

1.26 "Commercial Year" means (a) for the sole purpose of calculating whether an Event Milestone under Section 5.2 has been achieved, the twelve (12) month period commencing on either (i) the Launch date, or (ii) January 1 of the subsequent Calendar Year, if during such first twelve (12) month period starting from the Launch date, Event Milestone 5 has not been achieved; or (b) for all other purposes, the period commencing on the Launch Date and ending twelve (12) months after the first day of the subsequent Calendar Quarter, and (in each case (a) and (b)) any subsequent twelve (12) month period.

1.27 "Commercialization" means any and all activities directed to and including marketing, promoting, advertising, distributing, disposing, offering for sale, selling, Labelling and Packaging, final product release testing, exporting and importing of a Licensed Product for commercial sale (to the extent applicable). When used as a verb, "Commercialize" means to engage in Commercialization.

1.28 "Commercialization Plan" shall have the meaning set forth in Section 3.7(a).

1.29 "Commercially Reasonable Efforts" means, with respect to the efforts to be expended by a Party with respect to the objective that is the subject of such efforts, reasonable, good faith efforts and resources to accomplish such objective that such Party would normally use to accomplish a similar objective under similar circumstances, it being understood and agreed that with respect to the Commercialization of the Licensed Product in the Field in the Territory by Chiesi, such efforts shall be similar to those efforts and resources consistent with the usual practice of Chiesi in pursuing the Commercialization of drug products owned by it or to which it otherwise has rights that are of similar market potential as a Licensed Product in the Territory, taking into account all relevant factors, including the orphan drug status (if any) of the Licensed Product and other regulatory matters, safety and efficacy matters, product labeling or anticipated labeling, pricing, present and future market potential, past performance of the Licensed Product, past performance of Chiesi's own drug products that are of similar market potential (taking into account that the Licensed Product is intended for the treatment of a rare disease), financial return [***], medical and clinical considerations, present and future regulatory environment and competitive market conditions, all as measured by the facts and circumstances at the time such efforts are due. It is anticipated that the level of effort constituting Commercially Reasonable Efforts may change over time. With respect to the Commercialization of the Licensed Product in the Field in the Territory by Chiesi, such efforts shall include [***]. With respect to the [***] and each subsequent Commercial Year thereafter during the Term, on an annual basis and at least one hundred and twenty (120) days prior to the start of such Commercial Year, the Parties shall, through the Steering Committee, discuss and mutually agree, acting reasonably and in good faith, upon the appropriate minimum number of FTEs to apply during such upcoming Commercial Year, with the intent that such number reflect the number of FTEs needed to successfully Commercialize the Licensed Product in the Territory given the then-current market conditions, and taking into account each of the other relevant factors set forth in the first sentence of this Section 1.29. In the event that the Parties are unable to agree upon the appropriate minimum number of FTEs to apply during such Commercial Year at least sixty (60) days prior to the start of such Commercial Year, such matter shall be escalated to the Parties' respective Chief Executive Officers, who shall attempt to resolve such issue within a subsequent thirty (30) day period.

1.30 "Competing Product" means [***].

1.31 "Competing Product Patent" means any Third Party Patent or Patent Application owned or controlled by a Third Party that (itself or through an affiliate) is selling, or has sold, a Competing Product anywhere in the world.

1.32 "Compliance Records" shall have the meaning assigned to it in Section 6.6.

1.33 "Compound" means (a) a plant cell-expressed recombinant form of human alpha-Galactosidase-A, including pegunigalsidase alfa (PRX-102) and (b) any analogs, derivatives and variants thereof.

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

1.34 "Confidential Information" means the Protalix Confidential Information or the Chiesi Confidential Information, as applicable.

1.35 "Control" or "Controlled" means, with respect to any compound, material, information, 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, information, 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 Effective Date or (b) any Law applicable to such license or sublicense.

1.36 "Country" means any generally recognized sovereign entity.

1.37 "CMC" means, in respect of a regulatory filing, "Chemistry, Manufacturing, and Controls".

1.38 "Deferred Milestone" shall have the meaning assigned to it in Section 5.2(d).

1.39 "Development" or "Develop" means conducting non-clinical (including pre-clinical studies and CMC activities) and clinical trials (including the Ongoing Clinical Studies and the [***]), collecting, validating and analyzing pre-clinical and clinical trial data, preparing and submitting any regulatory filings prior to obtaining Regulatory Approval, preparing the clinical and Manufacturing portions of any regulatory filing seeking Regulatory Approval (including portions relating to CMC), and regulatory affairs related to the foregoing. When used as a verb, "Develop" means to engage in Development. For clarity, Development does not include any regulatory affairs or commitments in respect of the Licensed Product in the Territory following Regulatory Approval for such Licensed Product in the Territory, or any of the foregoing in connection therewith. When used as a verb, "Developing" means to engage in Development.

1.40 "Development Costs" means Protalix's fully-loaded costs related to the Development of (and obtaining Regulatory Approval from the FDA for) the Licensed Product, excluding Patent Costs, and including any (a) direct, out-of-pocket costs and expenses, including clinical or medical grants, clinical laboratory fees, positive controls and the cost of pre-clinical and clinical studies conducted and services provided by contract research organizations, and (b) the conduct of clinical studies, including costs and expenses associated with data management, statistical designs and studies, document preparation and any and all other costs and expenses associated with preparing and submitting regulatory filings, obtaining (including, solely with respect to approvals granted upon specific conditions requiring the conduct of specified additional required studies to maintain such granted Regulatory Approval, maintaining) Regulatory Approval for the Licensed Product, and the conduct of the clinical Development program for the Licensed Product, including as set out in the Development Plan [***].

1.41 "Development Costs Cap" shall have the meaning assigned to it in Section 5.3(c).

1.42 "Development Plan" shall have the meaning assigned to it in Section 3.1.

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

1.43 "Drug Substance" means the Compound component of a pharmaceutical drug product.

1.44 "Drug Product" means unlabeled vials of Licensed Product [***], but not Labeling and Packaging.

1.45 "Early Access Program" means any program to provide patients with the Licensed Product prior to Regulatory Approval and prior to Launch in the Territory. Early Access Programs include, for example, any expanded compassionate use or expanded access programs authorized by the FDA in the Territory.

1.46 "Effective Date" means the date of this Agreement.

1.47 "EMA" means the European Medicine Agency or any successor agency thereto.

1.48 "European Union" or "EU" means the Countries that are members of the European Union as of the Effective Date or that become members of the European Union thereafter, and includes, for the avoidance of doubt, any Countries that as of the Effective Date, or at any point during the Term thereafter, cease being members of the European Union, but that remain subject to any applicable Law of the EU.

1.49 "Event Milestone" shall have the meaning set forth in Section 5.2(a).

1.50 "Event Milestone 1", "Event Milestone 2", "Event Milestone 3", "Event Milestone 4", "Event Milestone 5", "Event Milestone 6", "Event Milestone 7", "Event Milestone 8", "Event Milestone 9", "Event Milestone 10", "Event Milestone 11", "Event Milestone 12", "Event Milestone 13", "Event Milestone 14", "Event Milestone 15", "Event Milestone 16", "Event Milestone 17", "Event Milestone 18", and "Event Milestone 19", shall each have the meanings assigned to those terms in Section 5.2(a).

1.51 "Event Milestone Payments" means the amounts set forth in Section 5.2(a) opposite the respective Event Milestones, subject to Sections 5.2(b), 5.2(c) and 5.2(d).

1.52 "Extension Studies" means any extension study that allows patients to continue to receive study treatment when the original Ongoing Clinical Studies into which they were enrolled have reached their designated end-dates.

1.53 "Ex-US Agreement" shall have the meaning assigned to it in the Recitals.

1.54 [***]

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

1.55 "Facility" means, as applicable, Protalix's Manufacturing facility and such other facilities used by Protalix (or its Affiliates, permitted licensees, permitted sublicensees or designees [***]) in the Manufacture or storage of (a) Drug Substance, (b) Drug Product or (c) materials utilized in the Manufacture of Drug Substance or Drug Product.

1.56 "Failure to Supply" shall have the meaning assigned to it in Section 4.14(a).

1.57 "FDA" means the United States Food and Drug Administration (or any successor agency thereto).

1.58 "Field" means enzyme replacement therapy for the treatment of Fabry Disease.

1.59 [***]

1.60 [***]

1.61 "Financial Records" shall have the meaning assigned to it in Section 6.6.

1.62 "Force Majeure Event" shall have the meaning assigned to it in Section 15.1.

1.63 "Forecast" shall have the meaning assigned to it in Section 4.5(a).

1.64 "FTE" shall mean one or more persons allocated on a full-time basis to the Commercialization of the Licensed Product in the Territory (both at a headquarter and country level, and including, for clarity, any product specialists, key asset managers, sales representatives, medical science liaisons, or medical, regulatory, market access and marketing personnel).

1.65 "GAAP" means United States generally accepted accounting principles consistently applied.

1.66 "Good Manufacturing Practices" or "GMP" means all applicable Good Manufacturing Practices including, (i) 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 European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice, (ii) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210 and 211, (iii) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, (iv) the principles detailed in the ICH Q7A guidelines, and (v) the equivalent Laws in any relevant Country, each as may be amended and applicable from time to time.

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

1.67 "Governmental Authority" means any court, agency, department, authority or other instrumentality of any national, supra national, state, county, city or other political subdivision.

1.68 "ICC Rules" shall have the meaning assigned to it in Section 14.2(b).

1.69 "IND" means (i) an investigational new drug application as defined in 21 CFR 312.3 and all amendments and supplements thereto filed with the FDA or (ii) an equivalent application filed with any equivalent foreign agency or Governmental Authority including all documents, data and other information concerning use of an investigational pharmaceutical product which are necessary for gaining authorization from such equivalent foreign agency or Governmental Authority to ship and use such product in clinical investigations.

1.70 "Indemnified Party" shall have the meaning assigned to it in Section 13.4(a).

1.71 "Indemnifying Party" shall have the meaning assigned to it in Section 13.4(a).

1.72 "Indenture" means the Indenture, dated as of December 7, 2016, as amended, supplemented or restated from time to time, among Protalix Parent, as Issuer, the Guarantors party thereto, The Bank of New York Mellon Trust Company, N.A., as Trustee, and Wilmington Savings Fund Society, FSB, as Collateral Agent.

1.73 "Indenture Collateral Agent" means Wilmington Savings Fund Society, FSB, as Collateral Agent under the Indenture and the Indenture Security Documents, or any successor thereto.

1.74 "Indenture Security Documents" means the security agreements and other documentation defined as "Security Documents" under the Indenture.

1.75 "Indenture Trustee" means The Bank of New York Mellon Trust Company, N.A., as Trustee under the Indenture, or any successor thereto.

1.76 "Initial Forecast" shall have the meaning assigned to it in Section 4.5(a).

1.77 "Initiation" means, with respect to the Phase 1 Clinical Trial for a New Use, the first study-specific screening activities.

1.78 "IRB" means an Institutional Review Board within the meaning of 45 C.F.R. part 46. For the avoidance of doubt, similarly constituted bodies identified as independent ethics committees, ethical review boards, or research ethics boards shall, in each case, constitute IRBs for the purposes of this Agreement.

1.79 "Israeli Security Trustee" means Altshuler Shaham Trusts Ltd. as in its capacity as Security Trustee under the Israeli law governed Security Documents.

1.80 "Invention" means all inventions, discoveries and improvements (whether or not patentable) that are made, conceived, or first actually reduced to practice by or on behalf of a Party or any of its Affiliates.

1.81 "Joint Legal Counsel" shall have the meaning assigned to it in Section 14.3(a).

1.82 "Joint Legal Opinion" shall have the meaning assigned to it in Section 14.3(a).

1.83 "Label" means, with respect to a Licensed Product, all labels and other written, printed, or graphic matter (a) on the Licensed Product containers or wrappers, or (b) accompanying the Licensed Product.

1.84 "Labeling and Packaging" means the final product labeling and packaging of the Drug Product, including materials to be inserted such as patient inserts, patient medication guides, professional inserts and any other written, printed or graphic materials accompanying the Drug Product.

1.85 "Launch" with respect to the Territory, means the first shipment of a Licensed Product in commercial quantities for commercial sale by Chiesi or its Affiliates to a Third Party in the Territory after receipt of the first Regulatory Approval for such Licensed Product in the Territory. "Launched", when used in respect of the Licensed Product, means that the Launch of such Licensed Product has already occurred in the Territory.

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

1.87 "Licensed Product" means any finished dosage form of a drug product that contains the Drug Substance and either: (a) the manufacture, sale, offer for sale, importation, or use of which (i) would, absent the license granted by Protalix to Chiesi herein, infringe at least one Valid Claim of a Protalix Patent Right or (ii) embodies, incorporates or uses Protalix Technology, or (b) is supplied by Protalix to Chiesi under this Agreement as Drug Product or, after the [***] (subject to Chiesi performing Labeling and Packaging in respect of such Drug Product and, after [***].

1.88 "Long Range Forecast" shall have the meaning assigned to it in Section 4.5(b).

1.89 "Manufacture" or "Manufacturing" means all activities related to the manufacturing of the Drug Substance, Drug Product or Licensed Product (as applicable), and/or any ingredient thereof, including manufacturing for clinical use or commercial sale, in-process and finished product testing, the final product labeling and packaging of the product, 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.

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

1.90 "Manufacturing Certificate of Analysis" shall have the meaning assigned to it in Section 4.8(a)(i).

1.91 "Material Change" shall have the meaning assigned to it in Section 7.2(a).

1.92 "Maximum Order Quantity" shall have the meaning assigned to it in Section 4.6(i).

1.93 "Minimum Batch Size" means the minimum batch size for Drug Product (as may be updated by Protalix from time to time, in its sole discretion for any variance of [***] or less, and only with Chiesi's prior consent for any variance of more than [***], such consent not to be unreasonably withheld, conditioned or delayed), which currently is [***] vials of Licensed Product.

1.94 "Minimum Payment" shall have the meaning assigned to it in Section 4.6(h).

1.95 "NDA" means a New Drug Application or Biologics License Application (as applicable) filed with the FDA with respect to a drug product or an analogous application or filing with any Regulatory Authority outside of the United States (including any supra-national entity such as the European Union) for the purpose of obtaining approval to market and sell a drug product in such jurisdiction.

1.96 "Negotiation Period" means the ninety (90)-day period beginning on the date as set forth in Section 2.5(b) of the Ex-US Agreement.

1.97 "Net Sales" means, with respect to a Licensed Product, the gross amounts invoiced by Chiesi or its Affiliates for sale of Licensed Product, less the following customary deductions, determined in accordance with GAAP and standard internal policies and procedures and accounting standards and methods consistently applied throughout Chiesi's organization, to the extent specifically and solely allocated to such Licensed Product and actually taken, paid, accrued, allowed, included or allocated: [***]

1.98 "New Indication" means a distinct type of disease or medical condition in humans to which a Licensed Product is directed that is not the Field.

1.99 [***]

1.100 "New Use" shall have the meaning assigned to it in the Ex-US Agreement.

1.101 "Notice of Non-Conformance" shall have the meaning assigned to it in Section 4.8(a)(i).

1.102 "Ongoing Clinical Study" means [***].

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

1.103 "Orphan Drug Designation" shall have the meaning set out in 21 C.F.R. Part 316.

1.104 "Other Patent Challenge" shall have the meaning assigned to it in Section 2.7(c).

1.105 "Outside of the Scope Product" shall have the meaning assigned to it in Section 7.2(a).

1.106 "Patent Application" means any application for a Patent.

1.107 "Patent Costs" means any and all costs and expenses incurred by Protalix in respect of the exercise of any of its rights and obligations under Section 7 of this Agreement.

1.108 "Patent Rights" means Patents and Patent Applications.

1.109 "Patents" means issued patents, whether domestic or foreign, including all continuations, continuations-in-part, divisions, provisionals and renewals, and letters of patent granted with respect to any of the foregoing, patents of addition, supplementary protection certificates, registration or confirmation patents and all reissues, re-examination and extensions thereof.

1.110 "Patent Ownership Challenge" shall have the meaning assigned to it in Section 2.7(a).

1.111 "PCT" means the Patent Cooperation Treaty, opened for signature June 19, 1970, 28 U.S.T. 7645.

1.112 "Pediatric Study" means the pediatric clinical study of the Licensed Product that, as of the effective date of the ex-US Agreement, was being designed and prepared by Protalix, to be conducted in accordance with Section 3.2(d).

1.113 "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.

1.114 "Pharmacovigilance Agreement" shall have the meaning assigned to it in Section 3.6(f).

1.115 "Phase 1 Clinical Trial" means a human clinical trial of the initial Licensed Product that would satisfy the requirements of 21 C.F.R. § 312.21(a) or any other equivalent foreign requirements.

1.116 "Post-Approval Studies" means any pre-clinical or clinical studies for a Licensed Product (or for the Drug Substance therein) commenced after receipt of Regulatory Approval for such Licensed Product, that are not [***].

1.117 "Price" means the price to be charged by Protalix and paid by Chiesi for Drug Product [***] sold by Protalix to Chiesi under this Agreement as specifically determined in accordance with Section 4.6.

1.118 "Product Marks" shall have the meaning assigned to it in Section 3.9(b).

1.119 "Product Specifications" means those Manufacturing, performance, quality - control release, and other specifications for Drug Substance, Drug Product or Licensed Product in the Territory, which are initially as set forth in the applicable Regulatory Approval for a Licensed Product, as such specifications may be amended from time to time pursuant to the terms of this Agreement.

1.120 "Protalix Chair" means one of the Protalix representatives on the Steering Committee designated by Protalix as Protalix's chair for Steering Committee Meetings.

1.121 "Protalix Confidential Information" means all information or data of a proprietary or confidential nature relating to the Protalix Technology, Compound or Licensed Product as well as any other information, including proprietary information and materials, regarding the business, operations, research, Technology and the supply, Manufacture, Development and Commercialization activities of Protalix, whether in oral, written, graphic, machine-readable form, or any other form, (provided that data and information disclosed orally or visually are confirmed in writing by Protalix within thirty (30) days after the date of such disclosure), disclosed and/or made available by or on behalf of Protalix to Chiesi, Chiesi's Affiliates, and its and their respective directors, officers, employees, consultants, contractors and agents or otherwise acquired by any such Persons as a result of or in connection with this Agreement and/or the Parties' discussions (whether prior to the execution hereof or thereafter). Notwithstanding the foregoing, unmarked information and un-confirmed information will be considered Protalix Confidential Information under this Agreement if a reasonable person familiar with the Licensed Product and given the nature of information and the circumstances of disclosure would consider such information to be confidential. Such information shall not be considered to be Protalix Confidential Information to the extent that such information is: (a) as of the date of disclosure known to Chiesi or its Affiliates, as demonstrable in any tangible medium in existence at the time of disclosure; or (b) wholly disclosed in published literature, or otherwise is or becomes generally known to the public through no breach by Chiesi of this Agreement; or (c) obtained by Chiesi or its Affiliates from a Third Party free from any obligation of confidentiality to Protalix; or (d) independently developed by Chiesi or its Affiliates without use of or reference to the Protalix Confidential Information.

1.122 "Protalix Parent" means Protalix Biotherapeutics, Inc.

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

1.123 "Protalix Patent Rights" means all Patent Rights owned or otherwise Controlled by Protalix or any of its Affiliates 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 (or, with respect to the use of the term Protalix Patent Rights in Section 7 of this Agreement only, of a recombinant form of alpha-Galactosidase), including the Patent Rights listed in Exhibit A.

1.124 "Protalix System Patent Rights" means Protalix Patent Rights that relate primarily to the System.

1.125 "Protalix Trademarks" shall have the meaning assigned to it in Section 3.10.

1.126 "Protalix Technology" means any Technology owned or otherwise Controlled by Protalix or any of its Affiliates as of the Effective Date or at any time during the Term that is necessary or useful for the Development, Manufacture, use or Commercialization of Compound, Drug Substance or a drug product that contains Drug Substance, including the System.

1.127 "Purchase Order" shall have the meaning assigned to it in Section 4.5(a).

1.128 "Quality Agreement" means the Quality Agreement(s) to be entered into (or already entered into) between Protalix and Chiesi under the Ex-US Agreement, with respect to the Drug Product [***].

1.129 [***]

1.130 [***]

1.131 "Reconciliation Adjustment" shall have the meaning assigned to it in Section 4.6(h).

1.132 "Referent Person" shall have the meaning assigned to it in Section 8.5.

1.133 "Registry" shall mean an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes and meets the requirements of the applicable Regulatory Authority.

1.134 "Reimbursed Party" shall have the meaning assigned to it in Section 5.3(i).

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

1.135 "Reimbursing Party" shall have the meaning assigned to it in Section 5.3(i).

1.136 "Regulatory Approval" means any and all approvals, or authorizations of a Regulatory Authority, that are necessary for the commercial Manufacture, distribution, use, marketing or sale of a drug product in the Territory, including but not limited to any NDAs.

1.137 "Regulatory Authority" means, in respect of a particular Country or jurisdiction, the Governmental Authority having responsibility for granting Regulatory Approvals in such Country or jurisdiction.

1.138 "Regulatory Exclusivity" means any rights or protections which are recognized, afforded or granted by the FDA, in association with the Regulatory Approval of a Licensed Product, providing such Licensed Product: (a) a period of marketing exclusivity, during which the Regulatory Authority recognizing, affording or granting such marketing exclusivity will refrain from either reviewing or approving a marketing authorization application or similar regulatory submission, submitted by a Person other than Chiesi or its Affiliates seeking to market a drug product in which the Drug Substance is the primary ingredient, or during which such an application or submission may be reviewed or approved by a Regulatory Authority, but the product may not be placed on the market or (b) a period of data exclusivity, during which a Person, other than Chiesi or its Affiliates, seeking to market a drug product in which the Drug Substance is the primary ingredient, is precluded from either referencing or relying upon a Licensed Product's clinical dossier or relying on previous findings of safety or effectiveness with respect to a Licensed Product to support the submission, review or approval of a marketing authorization application or similar regulatory submission before the applicable Regulatory Authority.

1.139 [***]

1.140 [***]

1.141 [***]

1.142 "Safety Stock" shall have the meaning assigned to it in Section 4.12(a).

1.143 "Safety Stock Amount" shall have the meaning assigned to it in Section 4.12(a).

1.144 "Shortage" shall have the meaning assigned to it in Section 4.11.

1.145 "Side Letter" means that certain Side Letter to this Agreement effective on the Effective Date and made by and between Chiesi and Protalix.

1.146 "Standby License" shall have the meaning assigned to in Section 2.2(d).

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

1.147 "Steering Committee" shall have the meaning assigned to it in Section 3.3(a).

1.148 "Steering Committee Meeting" shall have the meaning assigned to it in Section 3.3(b).

1.149 "Sublicense" means the grant by Chiesi of a sublicense under, or an agreement of Chiesi not to assert, any of the rights licensed by Protalix to Chiesi pursuant to Section 2.1.

1.150 [***]

1.151 "System" means Protalix's proprietary protein expression system, ProCellEx™.

1.152 "Technology" means proprietary 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, including any intellectual property rights embodying any of the foregoing, but excluding Patent Rights.

1.153 "Term" shall have the meaning assigned to it in Section 11.

1.154 "Territory" means the United States.

1.155 "Third Party" means any Person other than Chiesi, Protalix, or any of their respective Affiliates.

1.156 "Third Party Claim" shall have the meaning assigned to it in Section 13.4(a).

1.157 "Third Party License" means each license agreement between Protalix and a Third Party pursuant to which or from which Protalix licenses Protalix Patent Rights or Protalix Technology, including those listed on Exhibit B.

1.158 "United States" or "U.S." means the United States of America, its territories and possessions.

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

1.159 "Valid Claim" means (a) a claim of an issued and unexpired Patent (including the term of any patent term extension, supplemental protection certificate, renewal or other extension) which has not been held unpatentable, invalid or unenforceable in a final decision of a court or other Governmental Authority of competent jurisdiction from which no appeal may be or has been taken, and which has not been admitted to be invalid or unenforceable through reissue, re-examination or disclaimer; or (b) a claim of a Patent Application, which claim has been pending less than seven (7) years from the original priority date of such claim in a given jurisdiction, unless or until such claim thereafter issues as a claim of an issued Patent (from and after which time the same shall be deemed a Valid Claim subject to paragraph (a) above).

1.160 "Yearly Reconciliation" shall have the meaning assigned to it in Section 4.6(h).

1.161 Construction. 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" or "Schedule" refer to an Article or Section of, or any Exhibit 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.

Section 2. LICENSE

2.1 Exclusive License. Subject to the terms of this Agreement, including Section 2.2, Protalix hereby grants to Chiesi, and Chiesi hereby accepts, an exclusive (including as to Protalix and its Affiliates, except as set forth in Section 2.2), non-transferable, license during the Term, solely in the Territory and within the Field, including the right to Sublicense to its Affiliates (solely as permitted under and in accordance with Section 2.4):

(a) under the Protalix Patent Rights to (i) Commercialize the Licensed Product in the Field in the Territory, (ii) on a non-exclusive basis, following the completion of [***] (if any), carry out [***] activities with respect to the Licensed Product in the Field in the Territory, and (iii) seek and obtain Regulatory Approval for the Licensed Product in the Field in the Territory (in each case, in accordance with Section 3); and

(b) to use Protalix Technology as necessary to (i) seek and obtain Regulatory Approval for the Licensed Product in the Field in the Territory, including following the transfer contemplated by Section 3.6(c), to prepare and submit any regulatory filings and communicate with Regulatory Authorities with respect to the Licensed Product in the Field in the Territory (in each case, in accordance with Section 3), (ii) following completion of the transfers contemplated by Section 3.6(d)(iv), on a non-exclusive basis, carry out its Commercial Medical Affairs and Pharmacovigilance responsibilities, (iii) on a non-exclusive basis, following the completion of [***], carry out [***] activities with respect to the Licensed Product in the Field in the Territory, and (iv) Commercialize the Licensed Product in the Field in the Territory.

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

2.2 Other License Provisions.

(a) The licenses granted to Chiesi pursuant to Section 2.1 shall be co-exclusive with Protalix to the extent it is necessary or useful for Protalix to perform its obligations under this Agreement.

(b) The Parties expressly acknowledge and agree that, the exclusivity grant in favor of Chiesi in Section 2.1 shall not be construed as limiting (i) Protalix's right to Develop or Manufacture the Licensed Product (or the Compound, Drug Substance or Drug Product for use in the Licensed Product), (ii) Protalix's right to Commercialize the Licensed Product outside of the Field or, subject to the Ex-US Agreement, outside of the Territory, or (iii) subject to the Ex-US Agreement, any of Protalix's rights in respect of the Licensed Product (including its rights under the Protalix Patent Rights) outside of the Territory.

(c) For purposes of clarity, Chiesi acknowledges that in the event Protalix does not have exclusive rights to Protalix Patent Rights or Protalix Technology licensed or obtained by Protalix from Third Parties vis à vis the Third Party licensor, Chiesi's rights to such Protalix Patent Rights or Protalix Technology under the sublicenses granted under Section 2.1 would not be exclusive vis à vis the Third Party licensor or its licensees (but would have the same scope of rights licensed or obtained by Protalix thereunder to the extent such rights are granted to Chiesi by Protalix hereunder and permitted to be granted by Protalix to Chiesi under such Third Party License).

(d) Protalix shall use Commercially Reasonable Efforts to obtain an agreement between Chiesi and such Third Party licensor pursuant to which, in the event that the applicable Third Party License is terminated for any reason, such Third Party licensor would grant Chiesi a license to the Protalix Patent Rights or Protalix Technology (as applicable) that Protalix has licensed from that Third Party licensor to the extent included in, and solely for the purpose of, the license granted to Chiesi hereunder (each such agreement, a "Standby License"), including approaching such Third Party licensor with respect thereto within thirty (30) days after the Effective Date.

2.3 Non-Assertion of Rights.

(a) During the Term, Chiesi shall not, and shall cause its Affiliates not to, assert any Patent Rights or Technology owned or Controlled by Chiesi and its Affiliates against Protalix, its Affiliates or permitted sublicensees for (i) exercising its rights and performing its obligations pursuant to this Agreement or (ii) subject to the Ex-Us Agreement, using, making, having made, selling, offering for sale, supplying, causing to be supplied and importing the Drug Substance or Licensed Product outside the Territory.

(b) The covenant not to sue in Section 2.3(a) shall inure to the benefit of any permitted assignee of this Agreement pursuant to Section 15.6.

(c) During the Term, Protalix shall not, and shall cause its Affiliates not to, assert any Protalix System Patent Rights owned or Controlled by Protalix and its Affiliates against Chiesi and its Affiliates for exercising its rights and performing its obligations pursuant to and in accordance with this Agreement and the license granted herein. Such covenant not to sue shall inure to the benefit of any permitted assignee of this Agreement pursuant to Section 15.6.

2.4 Sublicensing and Subcontracting.

(a) Chiesi may only grant Sublicenses to its Affiliates, which Sublicense shall automatically terminate when such Affiliate ceases to be an Affiliate of Chiesi, for the purposes of exercising, on behalf of Chiesi, any of the rights granted to Chiesi in Section 2.1 (other than the right to grant Sublicenses thereunder). Any sublicensee 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 Chiesi. To the extent that Chiesi wishes to grant a Sublicense other than in accordance with this Section 2.4(a), Chiesi must first obtain the express written consent of Protalix to such Sublicense in Protalix's sole discretion.

(b) Right to Subcontract. Each Party may, subject to Section 4.3 and Section 8, subcontract its rights and obligations under this Agreement to an Affiliate or Third Party as it would in the normal course of its business without the prior written consent of the other Party, except that Chiesi may not subcontract to any Third Party (including sub-distributors and contract sales organizations), without the prior written consent of Protalix, such consent not to be unreasonably delayed, withheld or conditioned, its rights or obligations to promote the Licensed Product (and the majority of the members of Chiesi's sales force shall be employees of Chiesi or its Affiliate).

2.5 Liability for Affiliates and Subcontractors

. Each Party shall ensure that each of its Affiliates and permitted subcontractors accepts and complies with all of the applicable terms and conditions of this Agreement as if such Affiliates or permitted subcontractors were Parties to this Agreement and each Party shall remain fully responsible and fully liable for its Affiliates' and permitted subcontractors' performance under this Agreement.

2.6 New Indications.

(a) As provided in the Ex-US Agreement, Protalix shall notify the Steering Committee, at least every six (6) months during the Term, of any material updates with respect to any material Development activities, with respect to the Licensed Product for a New Indication (a "New Use").

(b) [***]

(c) [***]

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

2.7 Patent Challenges.

(a) During the Term of this Agreement, Chiesi and its Affiliates hereby covenant and agree not to, directly or indirectly, commence any legal proceeding, or to, directly or indirectly, provide support or assistance in respect of any legal proceeding commenced by a Third Party, that challenges the ownership of any Protalix Patent Right, including any Protalix System Patent Right, to the extent such Protalix Patent Right relates to the Compound or Licensed Product or the Development, Manufacture or Commercialization of the Compound or Licensed Product (a "Patent Ownership Challenge").

(b) If Chiesi or its Affiliate directly or indirectly commences (or provides any support or assistance in respect of) any Patent Ownership Challenge or any Other Patent Challenge, Protalix shall have the right to immediately terminate this Agreement by written notice effective upon receipt by Chiesi. The foregoing right of Protalix to terminate this Agreement shall not apply to any such challenge that arises out of or is in connection with any legal action commenced by Protalix against Chiesi, in which Protalix asserts any Protalix Patent Rights or other Patent Rights against Chiesi, whether arising out of or in connection with this Agreement or otherwise.

(c) For the purpose of this Section 2.7, the term "Other Patent Challenges" means any legal proceeding that challenges the validity or enforceability of any Protalix Patent Right, including any Protalix System Patent Right, to the extent such Protalix Patent Right relates to the Compound or Licensed Product or the Development, Manufacture or Commercialization of the Compound or Licensed Product ("Other Patent Challenge").

(d) Without limiting the generality of the foregoing, Chiesi specifically agrees that filing a request for re-examination, knowingly copying patent claims so as to institute an interference, or filing an opposition with respect to any of the Protalix Patent Rights shall be deemed an Other Patent Challenge hereunder.

2.8 No Implied License. Except for the licenses and other rights expressly granted to Chiesi herein, all right, title and interest in and to the Protalix Patent Rights, Protalix Technology, and Protalix Confidential Information (and all modifications, derivatives and improvements thereof), and any other rights of Protalix and its Affiliates not expressly granted to Chiesi hereunder (including, for clarity, all of the foregoing with respect to any Outside of the Scope Products), shall remain solely with Protalix, its Affiliates and its Third Party licensors, as applicable. To the extent any such rights vest in Chiesi (by operation of Chiesi's exercise of its step-in rights under Section 3.2(b) or otherwise), then Chiesi shall, and hereby does, irrevocably assign all such right, title and interest in and to the Protalix Patent Rights, Protalix Technology, and Protalix Confidential Information (and all modifications, derivatives and improvements thereof) to Protalix, and hereby acknowledges and agrees that any such rights are and shall remain owned solely by Protalix. Except as expressly provided in this Section 2 or elsewhere in this Agreement, neither Party will be deemed by this Agreement to have been granted any license or other rights to the other Party's intellectual property rights, either expressly or by implication, estoppel or otherwise. Notwithstanding anything to the contrary in this Agreement, the Parties acknowledge and agree that the Development and Commercialization of any Outside of the Scope Products (including any New Uses) shall not be within the scope of the licenses granted to Chiesi pursuant to Section 2 hereunder (except as expressly provided in Section 2.6).

Section 3. DEVELOPMENT, REGULATORY APPROVALS AND MARKETING

3.1 Development Plan. For the avoidance of doubt, the development plan that has already been prepared by Protalix pursuant to the Ex-US Agreement, to describe the Development program of, and otherwise govern the Development of, the Licensed Product in the Field, including the continuing conduct by Protalix (subject to Section 3.2(d)) of each Ongoing Clinical Study (such plan, the "Development Plan"), shall apply equally to this Agreement. [***]

3.2 Development Responsibilities.

(a) Clinical Development by Protalix. Pursuant to the Development Plan, and subject to the oversight of the Steering Committee, Protalix will be responsible for the Development of the Licensed Product in the Field, including (subject to Section 3.2(d)) continuing to conduct the Ongoing Clinical Studies. Protalix will also be responsible for preparing and promptly submitting to Chiesi the clinical sections of any regulatory filings in respect of obtaining Regulatory Approval with the FDA for the Licensed Product and, subject to Chiesi's approval rights in respect of such regulatory filing as a whole, Protalix shall consider in good faith any proposed revision reasonably made by Chiesi thereto.

(b) Chiesi Step-in Right. Notwithstanding Section 3.2(a), in the event of a delay, for reasons within Protalix's reasonable control (and, for clarity, not for reasons outside Protalix's reasonable control, i.e., a Force Majeure Event [***], of more than [***] (as compared to the timelines expressly identified as "step-in" timelines in the Development Plan) that occurs in the course of conducting the Ongoing Clinical Studies and/or a [***] being conducted by Protalix, Chiesi shall have the right (subject to Section 5.3(h)) to assume responsibility for conducting, or having conducted on its behalf, and to be the sponsor of, such Ongoing Clinical Studies and/or [***] (as applicable), upon no less than sixty (60) days' prior written notice to Protalix. Promptly following Protalix's receipt of such notice, the Parties shall cooperate in good faith to develop a written plan for the orderly transfer of responsibility for conducting the Ongoing Clinical Studies and/or [***] to Chiesi, with due regard for patient safety and the rights of any subjects that are participants in the Ongoing Clinical Studies and/or the [***], and in compliance with all applicable Laws and agreements with Third Parties; provided, that Chiesi shall assume sole responsibility for the conduct of, and any liability arising out of, the conduct of the Ongoing Clinical Studies and/or [***] immediately upon the completion of such transfer, including responsibility for all Development Costs (subject to Section 5.3(h)).

(c) Chiesi's Regulatory Approval Responsibilities. Chiesi shall be responsible for conducting [***]. For the avoidance of doubt, Chiesi shall be solely responsible for conducting [***]. This Section 3.2(c) hereby amends, replaces and supersedes in its entirety Section 3.2(c) of the Ex-US Agreement, which shall be of no further force or effect.

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

(d) Pediatric Study. Notwithstanding anything to the contrary in this Agreement or the Ex-US Agreement, the Parties shall agree, through the Steering Committee, and in accordance with Section 3.3, on which Party will conduct the Pediatric Study.

(e) Extension Studies. Notwithstanding anything to the contrary in this Agreement or in the Ex-US Agreement, the Parties acknowledge and agree that (i) for the avoidance of doubt, the Extension Studies are and shall be deemed to be included in the definition of Additional Studies hereunder and under the Ex-US Agreement [***]; provided that Protalix shall conduct the Extension Studies (as Additional Studies) based on a protocol to be approved by Chiesi until Chiesi assumes responsibility for the conduct of the Extension Studies in accordance with this Section 3.2(e). [***]. Chiesi shall assume full control of and responsibility for the conduct of all Extension Studies relating to the Licensed Product in the Field as soon as reasonably practicable after the date on which the transfer contemplated in Section 3.6(c) occurs. Promptly following the Effective Date, the Parties shall cooperate in good faith to develop a written plan for the orderly transfer of responsibility for conducting the Extension Studies to Chiesi, including transfer of sponsorship thereof (subject to the transfer contemplated in Section 3.6(c)) and an interim report to be provided to Chiesi therefor, with due regard for patient safety and the rights of any subjects that are participants in the Extension Studies, and in compliance with all applicable Laws and agreements with Third Parties; provided that Chiesi shall assume sole responsibility for the conduct of such Extension Studies immediately upon the completion of such transfer.

(f) Chiesi's Post-Regulatory Approval Responsibilities. Except as described in Sections 3.2(a) and 3.2(b), immediately following obtaining Regulatory Approval for which Chiesi submitted a regulatory filing in its own name in the Territory, Chiesi will assume sole responsibility for (i) the Commercialization of the Licensed Product in the Field in the Territory, and (ii) all post-approval commitments in respect of the Licensed Product in the Field in the Territory, including interactions or communications with the FDA (subject to Section 3.6(g)), the conduct of any Post-Approval Studies (subject to Section 5.3(g)), pharmacovigilance reporting (subject to Section 3.6(f)), medical affairs (subject to Section 3.6(d)(iv)) and related requirements.

(g) Responsibility for Costs. Each Party's responsibility for paying the costs associated with such Development activities is set forth in Section 5.3.

(h) Rights Outside the Territory. Notwithstanding anything to the contrary herein, the Parties acknowledge and agree that, at all relevant times during the Term, any and all rights relating to the Compound, Drug Substance or Licensed Product in the Field outside of the Territory shall be governed exclusively by the Ex-US Agreement.

3.3 Steering Committee.

(a) Formation and Membership. Pursuant to and in accordance with the Ex-US Agreement, the Parties have formed (and shall maintain) a steering committee (the "Steering Committee"), which the Parties acknowledge and agree shall also address matters relating to the Territory pursuant to this Agreement, as provided in this Section 3.3. As provided in the Ex-US Agreement, the Steering Committee shall consist of three (3) representatives appointed by Protalix and three (3) representatives appointed by Chiesi; provided that at least one (1) person appointed by each Party is a senior officer of such Party, vested with the appropriate decision-making and resource-allocating authority, and the requisite experience, to participate in discussion of, and decide on, the matters set out in Section 3.3(c) below. Each Party shall nominate a representative as contact point to discuss the agenda (such representative, the "Alliance Manager"), who can be selected or not among the three members nominated by the Parties as Steering Committee representatives. As provided in the Ex-US Agreement, the Steering Committee shall be chaired by the Protalix Chair. From time to time, each Party may substitute its representatives on the Steering Committee in its sole discretion (but subject to the terms of this section and Section 3.3 of the Ex-US Agreement), effective upon written notice to the other Party of such change. Additional representatives or consultants may from time to time, in the Steering Committee's discretion, be invited to attend Steering Committee Meetings, subject to such representatives' and consultants' written agreement to comply with the requirements of Section 8.

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

(b) Meetings. During the Term, the Steering Committee shall meet at least once each Calendar Quarter or as otherwise determined by the Parties (each such meeting, a "Steering Committee Meeting"); provided that such meetings may be combined with the meetings provided for under the Ex-US Agreement (with matters discussed based on the relevant territory). As provided in the Ex-US Agreement, (i) upon the reasonable request of the Steering Committee, Protalix will provide written materials relating to its activities under the Development Plan in advance of a Steering Committee Meeting, (ii) all Steering Committee Meetings may be conducted in person, by videoconference or by teleconference at such times and such Chiesi or Protalix locations as shall be determined by the Steering Committee Alliance Managers, and (iii) in-person meetings of the Steering Committee shall be held at least once every six (6) months (unless otherwise agreed by the Parties) and will alternate between appropriate offices of each Party. The Parties shall each bear all expenses of their respective representatives relating to their participation on the Steering Committee. The members of the Steering Committee also may convene or be polled or consulted from time to time by means of telecommunications, video conferences, electronic mail or correspondence, as deemed necessary or appropriate.

(c) Responsibilities. In addition to the matters provided for under the Ex-US Agreement, the Steering Committee shall have the following roles and responsibilities in relation to the Territory:

(i) review and approve any material amendments to the Development Plan (subject to Section 3.3(d)). Any proposed material amendment to the Development Plan, including arguments to support such amendment, shall be made available to the Steering Committee with reasonable advance notice and at least five (5) Business Days ahead of the scheduled meeting;

(ii) provide reasonably detailed updates, data and other information regarding Protalix's progress in Developing the Licensed Product in the Field;

(iii) provide updates in respect of any New Use in accordance with Section 2.5 of the Ex-U.S. Agreement;

(iv) discuss the timing of transferring any regulatory filings in the Territory with respect to the Compound, Drug Substance, Drug Product or Licensed Product from Protalix to Chiesi in accordance with the terms of Section 3.6(c), and discuss and agree upon appropriate timelines for, and the responsibilities of each Party in respect of, preparing any regulatory filings for obtaining Regulatory Approval in the Territory. As part of such discussions, the Steering Committee shall discuss and agree on appropriate timelines and processes for the orderly transfer of all medical affairs functions from Protalix to Chiesi in accordance with Section 3.6(d)(iv);

(v) act as a forum pursuant to which the Parties will review and discuss plans and strategies relating to (x) the Development of the Licensed Product in the Field, (y) regulatory matters with respect to the Licensed Product in the Field in the Territory, and (z) Commercialization of the Licensed Product in the Field in the Territory to ensure aligned communication at medical congresses and other scientific events as well as scientific publication plans;

(vi) modify the division of regulatory responsibilities as between the Parties in accordance with Section 3.6(d)(v);

(vii) subject to the terms of Section 8.5, review and/or approval of each Party's scientific publication plans;

(viii) oversee any Early Access Programs for the Licensed Product in the Field in the Territory;

(ix) review and agree upon the final version of the Initial Commercialization Plan, in accordance with Section 3.7(a), and review and provide comment upon any proposed revisions to, or any subsequent versions of, the Commercialization Plan (such comments to be considered in good faith by Chiesi);

(x) subject to Section 4.8(c), review and in good faith seek to resolve any disputes regarding any Notice of Non-Conformance issued in respect of a shipment of Drug Substance or Drug Product under the terms of this Agreement;

(xi) subject to Section 7.6(a), discuss any pertinent Third Party Patent Rights and decide upon whether a license to or acquisition of such Third Party Patent Rights or Technology is appropriate;

(xii) in the event the Ex-US Agreement expires or is terminated, discuss the possibility, from time to time, of sharing Licensed Product positioning and promotional materials for the Licensed Product in the Field, inside and outside the Territory;

(xiii) define the manner and timelines for Chiesi's access to sites and records of the Ongoing Clinical Studies and [***] conducted by Protalix;

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

(xiv) appoint the Referent Persons in accordance with Section 8.5;

(xv) establish, if deemed necessary, the creation of a Joint Project Team ("JPT") to oversee operations or activities. The composition of the JPT will be decided by the Steering Committee according to the type of activity and decision making in accordance with Section 3.3(d). The JPT shall be comprised of representatives from each Party with appropriate competence and level of decision-making authority. The JPT shall meet with a frequency to be agreed on by the Parties; and

(xvi) such other roles and responsibilities provided for in this Agreement or as may be assigned to the Steering Committee in writing by mutual agreement of the Parties.

(d) Decision-Making by the Steering Committee. All decisions of the Steering Committee made pursuant to this Agreement shall be made by consensus with each Party having one vote; provided, however, that in the event of a disagreement between Chiesi and Protalix with respect to any such proposed decision for which another decision-making mechanism is not expressly provided for herein and subject to the relevant provisions hereunder:

(i) the Chiesi Chair shall have the final decision-making authority with respect to (A) Commercialization of the Licensed Product in the Field in the Territory, (B) regulatory plans and strategies relating to the Licensed Product in the Field in the Territory (but excluding, for the avoidance of doubt, any clinical matters relating to the Licensed Product in the Field), (C) following Launch, Commercial Medical Affairs and Pharmacovigilance in the Territory, and (D) at any point after six (6) months following the Effective Date, any and all regulatory matters concerning the Licensed Product, including in respect of any Regulatory Approvals, associated regulatory filings, or post-approval communications with or requirements of the FDA (but excluding, for the avoidance of doubt, any clinical matters relating to the Licensed Product in the Field), subject to the obligation to consider the other Party's comments in good faith [***];

(ii) the Protalix Chair shall have the final decision-making authority with respect to (A) any regulatory matters concerning the Licensed Product until six (6) months after the Effective Date, and any medical affairs and pharmacovigilance functions prior to the transfers contemplated in Section 3.6(d) (but excluding, for the avoidance of doubt, any clinical matters relating to the Licensed Product in the Field), subject to the obligation to consider the other Party's comments in good faith [***], (B) the Protalix Patent Rights and Protalix Technology and Protalix's rights in or to the Protalix Patent Rights and Protalix Technology, (C) any CMC (and pre-clinical) matters in respect of the Licensed Product; provided that neither Party shall be permitted to commence any new preclinical activities in respect of the Licensed Product in the Field without first reaching agreement with the other Party as to the conduct of such preclinical activities, and (D) any [***] or other issues relating to the Licensed Product outside the Field; and

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

(iii) in respect of all clinical matters relating to the Licensed Product in the Field: (1) for any such matter relating to the Bridge Study or that otherwise do not affect Chiesi's rights in the Territory in any material respect, the governance principles set out in Section 3.3(d) of the Ex-US Agreement shall apply, (2) for any such matter relating to the Extension Studies, the Chiesi Chair shall have the final decision-making authority, and (3) for so long as this Agreement is in effect, notwithstanding anything in the contrary in the Ex-US Agreement, for all other such matters, neither Party shall have final decision-making authority with respect to any such clinical matters relating to the Licensed Product in the Field, and such matters shall be resolved by the Parties by consensus through the Steering Committee within ninety (90) days of such matter first being brought to the attention of the Steering Committee. In the event that the Parties are unable to resolve any such clinical matter by consensus through the Steering Committee within such ninety (90) day period, such matter shall be escalated to the Parties' respective Chief Executive Officers, who shall attempt to resolve such issue within a subsequent thirty (30) day period.

(iv) in the event of a disagreement in respect of a matter unrelated to the subject-matter of Sections 3.3(d)(i), 3.3(d)(ii) or 3.3(d)(iii), such matters shall be subject to the escalation and dispute resolution procedures set out in Section 14.2.

For the avoidance of doubt, to the extent that Protalix, in its sole discretion, deems it necessary due to a request or demand of a Regulatory Authority (but only where such request is mandatory or where failure to comply with such request could result in a penalty or actions against Protalix being imposed by such Regulatory Authority or a violation of applicable Law) or identified and immediate risk to patient safety, Protalix shall have the sole authority and the exclusive right to decide any matter in respect of the Development of the Licensed Product in the Field (other than with respect to (i) approving regulatory plans and strategies, and (ii) preparing and submitting regulatory filings and obtaining Regulatory Approvals after the transfer contemplated in Section 3.6(c)) without the approval of or any decision by the Steering Committee; provided, however, that Protalix shall use its reasonable efforts to provide notice to, and consult with, members of the Steering Committee, prior to exercising such discretion.

(e) Minutes. As provided in the Ex-US Agreement, (i) the Alliance Managers will coordinate and alternate in preparing draft of the minutes collecting input from the attendees and distributing to all members of the Steering Committee the final minutes of each meeting reasonably promptly after a Steering Committee Meeting, (ii) such minutes will report in reasonable detail actions taken by the Steering Committee during such meeting, issues requiring resolution and resolutions of previously reported issues, and (iii) such minutes will be reviewed and, if reasonably complete and accurate, signed by one Steering Committee member from each Party.

3.4 Records. During the Term, each Party will prepare and maintain accurate records and books relating to the progress and status of its activities under the Development Plan and otherwise in relation to the Development of the Drug Substance and Licensed Product.

3.5 Diligence. Subject to Chiesi's compliance with Section 5.3, Protalix will use Commercially Reasonable Efforts to carry out the Development Plan in order to Develop the Licensed Product in the Field in the Territory (subject to Section 3.2(d)). Subject to Protalix's compliance with Section 3.6(c), Chiesi will use Commercially Reasonable Efforts to seek as soon as reasonably practicable Regulatory Approval for the Licensed Product in the Field in the Territory. Chiesi will use Commercially Reasonable Efforts to Launch and Commercialize the Licensed Product in the Territory, promptly following such Regulatory Approval of the Licensed Product in the Field. The previous sentence above notwithstanding, if, prior to the submission of the NDA seeking Regulatory Approval for the Licensed Product in the Territory, Chiesi notifies Protalix in writing of any specific Competing Product Patents that, in Chiesi's good faith evaluation may pose risks in relation to Chiesi's Launch of the Licensed Product, and if, within ten (10) Business Days of receiving such written notice, Protalix provides Chiesi with written notice that Protalix desires to jointly engage a law firm to advise regarding the same in accordance with this Section 3.5: (i) Protalix and Chiesi promptly shall jointly engage a law firm of reputable stature and experienced in patent matters related to biologic products and approved by both Parties (such approval not to be unreasonably withheld, conditioned or delayed) to provide its legal opinion as to whether a judge or jury would be highly unlikely to conclude, in exercising its discretion in applying the applicable Laws to the facts, that the Launch of the Licensed Product in the Field in the Territory would infringe the Third Party Patent(s) or Patent Application(s) (which the law firm concludes could reasonably be issued within eighteen (18) months of the anticipated Regulatory Approval for the Licensed Product in the Territory) specified in such notice (with each Party paying an equal share of all costs, fees and expenses to be paid to such law firm therefor, and the law firm shall be instructed to try to provide such opinion within sixty (60) days of the engagement), and (ii) in the event that such law firm does not, prior to Regulatory Approval of the Licensed Product in the Field in the Territory, render a legal opinion that a judge or jury would be highly unlikely to conclude, in exercising its discretion in applying the applicable Laws to the facts, that the Launch of the Licensed Product in the Field in the Territory would infringe the Third Party Patent(s) or Patent Application(s) (which the law firm concludes could reasonably be issued within eighteen (18) months of the anticipated Regulatory Approval for the Licensed Product in the Territory) specified in such notice (including where Protalix fails to provide written notice that it desires to jointly engage a law firm in accordance with this Section 3.5), Chiesi will have the ultimate decision-making authority on the timing of the Launch (subject to Section 12.1(f)), based upon Chiesi's good faith evaluation of any risks associated with such specified Third Party Patents or Patent Applications. The Parties acknowledge and agree that (x) all communications with such law firm with respect to the foregoing, such law firm's related work product, and such opinion (the "Privileged Materials") shall be privileged and confidential and shall not be disclosed to anyone other than the Parties, except that a Party may disclose the Privileged Materials in confidence to a court, tribunal or other authority of competent jurisdiction if reasonably necessary to enforce its rights under this Agreement; provided that such Party seeks the highest level of confidential treatment for such Privileged Materials and limits the disclosure to the portion of the Privileged Material reasonably necessary to enforce its rights under this Agreement, and (y) prior to engaging the law firm, the Parties shall enter into a reasonable and customary joint defense agreement or common interest agreement; provided that, for the avoidance of doubt, the failure of the Parties to enter into such a joint defense agreement or common interest agreement shall not be construed or deemed as evidence of any waiver by any of the Parties of any applicable legal privilege or any of its or their rights in this Agreement, or as an indication that an applicable legal privilege has not attached to any Privileged Materials.

3.6 Regulatory Affairs.

(a) Copies of Regulatory Filings. Protalix shall provide to Chiesi, at Chiesi's expense, copies in electronic form of any regulatory filings in the Territory relating to the Licensed Product, including any clinical trial authorizations (including any regulatory filings in the Territory seeking approval to conduct a study or clinical trial of the Licensed Product), other filings with Regulatory Authorities, supplements or amendments thereto, written correspondence with Regulatory Authorities regarding such regulatory filings, and existing written minutes of meetings and memoranda of formal conversations between Protalix (including, to the extent practicable, Protalix's investigators) and Regulatory Authorities and any other document required to maintain the Regulatory Approvals (e.g. Trial Master Files) in Protalix's possession (but, for clarity, excluding any informal communications, i.e., e-mails) to the extent Protalix has the right to access and provide to Chiesi such materials.

(b) Regulatory Responsibilities. Subject to Section 3.3(d), and prior to the transfer contemplated in Section 3.6(c) below, Protalix shall, subject to Chiesi's direction and approval (by and through the Steering Committee or otherwise), be responsible for implementing all pre-Regulatory Approval regulatory plans and strategies for, and making any regulatory filings in respect of, the Licensed Product in the Field in the Territory (excluding, for the avoidance of doubt, any application to a Regulatory Authority seeking Regulatory Approval, which shall in each case, be in the name of, and submitted by, Chiesi). Without limiting the foregoing, following the transfer contemplated in Section 3.6(c):

(i) Chiesi (or one or more of its designated Affiliates) will own and be responsible for preparing, seeking, and submitting such regulatory filings as are necessary to obtain Regulatory Approval and then maintaining all Regulatory Approvals and any post-approval regulatory filings, for the Licensed Product in the Field in the Territory, including preparing all reports necessary as part of such Regulatory Approvals or post-approval regulatory filings. Protalix shall have the right and be responsible to prepare and promptly submit to Chiesi any non-clinical, clinical and Manufacturing portions (including CMC) of such regulatory filings and any related reports (subject to Chiesi's approval rights with respect to such regulatory filing as a whole), at Chiesi's sole cost and expense (unless such costs are Development Costs or other costs expressly addressed hereunder or by a separate agreement between the Parties). Protalix shall consider in good faith any proposed revision reasonably made by Chiesi thereto and Protalix shall otherwise provide such assistance as Chiesi reasonably requires, at Chiesi's sole cost and expense (unless such costs are Development Costs or other costs expressly addressed hereunder or by a separate agreement between the Parties), to obtain Regulatory Approvals for the Licensed Product in the Field in the Territory.

(ii) Following the transfer contemplated in Section 3.6(c), but in any event, no later than the grant of Regulatory Approval, Chiesi shall (A) subject to Section 5.3(e), assume sole responsibility for seeking authorization in respect of, conducting, and otherwise interacting with the FDA in respect of, any Post-Approval Studies, and (B) have the right to apply for, and secure, exclusivity rights that may be available under Law in the Territory, including any Regulatory Exclusivity. Protalix shall reasonably cooperate with Chiesi, and take such reasonable actions to assist Chiesi, at Chiesi's sole cost and expense, in obtaining such exclusivity rights in the Territory, as Chiesi may reasonably request from time to time.

For the avoidance of doubt (A) at all relevant times during the Term, Chiesi shall have the final decision-making authority in respect of all regulatory plans and strategies for the Licensed Product in the Field in the Territory; provided that Chiesi shall reasonably consider any comments on such plans and strategies that Protalix may communicate (through the Steering Committee or otherwise); and (B) following Regulatory Approval in the Territory, Chiesi shall be solely responsible for any such activities as are initiated after the date of such Regulatory Approval that would otherwise constitute Development activities had they been initiated prior to the grant of such Regulatory Approval.

(c) Transfer of Regulatory Filings. To the extent permitted by applicable Law, at a time to be agreed by and through the Steering Committee, with such time to be prior to any application to the FDA seeking Regulatory Approval for the Licensed Product in the Field in the Territory (and, in any event, but subject to the proviso set forth below, as soon as reasonably practicable after [***], and at Chiesi's sole cost and expense, Protalix shall assign and transfer to Chiesi Protalix's entire right, title and interest in and to all regulatory filings in the Territory with respect to the Compound, Drug Substance, Drug Product or Licensed Product in the Field, and shall perform all other actions reasonably requested by Chiesi to effect and confirm such assignment and transfer, at Chiesi's sole cost and expense; provided, however, that, for the avoidance of doubt, all right, title and interest in and to any clinical trial authorizations or other clinical regulatory filings as are necessary to support the continued conduct of and completion of the Ongoing Clinical Studies and any [***] shall remain vested in Protalix, until completion of such studies.

(d) Transfer of Regulatory Responsibilities. Subject to the terms of the Development Plan:

(i) The Parties shall cooperate through the Steering Committee to ensure that any such assignments and transfers under Section 3.6(c), do not impede Protalix's ability to conduct and complete the Ongoing Clinical Studies and [***]. After each such assignment and transfer is effective, Chiesi shall (and does hereby) grant Protalix a right to use and make reference to such regulatory filings so assigned and transferred (and any subsequent regulatory filings made or Regulatory Approvals in such Countries as are obtained by Chiesi in respect of the Licensed Product in the Field) as necessary for Protalix (x) to conduct and complete the Ongoing Clinical Studies and any [***], and (y) to conduct and complete any other clinical studies as necessary for Protalix to complete in order to file, and to file, for Regulatory Approval for (A) the Licensed Product outside the Territory in accordance with the Ex-US Agreement, or (B) any New Use (or other drug product containing the Drug Substance outside of the Field) anywhere in the world.

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

(ii) After such transfer of ownership of such regulatory filings relating to the Drug Substance (or Drug Product) as incorporated into the Licensed Product (and for the avoidance of doubt, excluding any regulatory filings and Regulatory Approvals with respect to the Drug Substance (or Drug Product) as part of any New Use), or Licensed Product in the Field in the Territory, during the Term, all regulatory filings seeking Regulatory Approval in the Territory and all subsequent post-approval regulatory filings that are filed with the FDA and which pertain to the Drug Substance (or Drug Product) as incorporated into the Licensed Product (and for the avoidance of doubt, excluding any such regulatory filings with respect to the Drug Substance (or Drug Product) as part of any New Use), or Licensed Product in the Field, in each case, in the Territory, shall be made in the name of Chiesi or its Affiliates in accordance with Section 3.6(e), and any Post-Approval Studies shall be conducted in the name of, and shall be the sole responsibility of, Chiesi and its Affiliates (subject to Section 5.3(g)).

(iii) For the avoidance of doubt, Protalix shall remain responsible for the preparation of any non-clinical (including pre-clinical and CMC), clinical, and Manufacturing portions of regulatory filings submitted by Chiesi seeking Regulatory Approval with the FDA, and shall otherwise provide reasonable assistance to Chiesi in finalizing such regulatory filings for submission to the FDA (in each case subject to Chiesi's approval rights with respect to the regulatory filing as a whole).

(iv) As part of the process of fixing a time for the regulatory transfer contemplated under Section 3.6(c), and subject to the terms of the Pharmacovigilance Agreement, the Steering Committee shall also set out a timeline for the orderly transfer of any pharmacovigilance (for post-Launch Commercialization) and medical affairs functions in the Territory from Protalix to Chiesi (as well as the role of primary contact for KOL management and patient advocacy) (such functions, following the completion of such transfer from Protalix to Chiesi, to be referred to as "Commercial Medical Affairs and Pharmacovigilance"), with such medical affairs functions to be fully transferred within twelve (12) months of the Effective Date, but prior to the grant of Regulatory Approval, and with such pharmacovigilance functions to be fully transferred upon Launch; provided, that until such time as each of the Ongoing Clinical Trials and any [***] are completed, and the clinical study reports for each such clinical study are finalized, Protalix shall retain responsibility for patient safety monitoring, and shall remain the primary contact with each applicable KOL, in respect of such clinical studies.

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

(v) Notwithstanding anything to the contrary herein, but subject to the terms of the Pharmacovigilance Agreement, the Steering Committee may by mutual agreement modify the division of regulatory responsibilities as between the Parties, including by having Protalix retain certain regulatory responsibilities following the transfer contemplated by Section 3.6(c), or by having Chiesi assume certain regulatory responsibilities prior to the transfer contemplated by Section 3.6(c) (including, for the avoidance of doubt, where such division of responsibilities differs from the terms of the Development Plan); provided, however, that (i) in no circumstances may Chiesi assume responsibility for or control over any clinical aspects of the Development Plan, including the conduct of the Ongoing Clinical Studies (except in the case of Chiesi exercising its step-in rights as provided for in Section 3.2(b) or the conduct by Chiesi of any Additional Studies, Pediatric Study, Registry or [***] as provided hereunder); and (ii) in any event, all regulatory responsibilities in respect of the Licensed Product in the Field in the Territory (including, for clarity, each of the transfers of regulatory responsibility contemplated in this Section 3.6), shall be completely assumed by Chiesi as soon as reasonably practicable after [***]; provided, that until such time as each of the Ongoing Clinical Trials and any [***] are completed, and the clinical study reports for each such clinical study are finalized, Protalix shall retain responsibility for patient safety monitoring, and shall remain the primary contact with each applicable KOL, in respect of such clinical studies.

(e) Rights of Reference and Access to Data. Chiesi shall (and does hereby) grant to Protalix a non-exclusive "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b), or an equivalent non-exclusive right of access/reference in the United States and in the EU and in each other Country (A) solely for use by Protalix in connection with the Development and/or Commercialization of any New Use (or other drug product containing the Drug Substance outside of the Field), to any data in any regulatory filing in the Territory Controlled by Chiesi that relates to the Drug Substance or Licensed Product, and (B) solely for use by Protalix in connection with the Development of drug products made using the System, to any safety data (but not efficacy data) in any regulatory filing in the Territory Controlled by Chiesi that relates to the Drug Substance or Licensed Product. Chiesi shall provide a signed statement to this effect, if requested by Protalix, in accordance with 21 C.F.R. § 314.50(g)(3), or otherwise provide appropriate notification of such right of Protalix to the applicable Regulatory Authority. To the extent Chiesi shall need an equivalent "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b), to exploit the rights granted hereunder in the Territory, Protalix shall (and does hereby) grant to Chiesi a non-exclusive Right of Reference, or an equivalent non-exclusive right of access/reference in the United States and in the EU and in each other Country, solely for use by Chiesi in connection with the Development and/or Commercialization of the Licensed Product in the Field in the Territory, and solely if and to the extent that Chiesi is authorized under this Agreement to conduct such Development and/or Commercialization, (A) to any data in any regulatory filing Controlled by Protalix that relates to the Drug Substance or Licensed Product, and (B) to any safety data (but not efficacy data) in any regulatory filing that relates to the Drug Substance or Licensed Product. Protalix shall provide a signed statement to this effect, if requested by Chiesi, in accordance with 21 C.F.R. § 314.50(g)(3), or otherwise provide appropriate notification of such right of Chiesi to the applicable Regulatory Authority.

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

(f) Pharmacovigilance. After the Effective Date [***], the safety units of each of the Parties shall meet and agree upon a written pharmacovigilance agreement that defines Chiesi's pharmacovigilance responsibilities for the post-Launch Commercialization of Licensed Product in the Territory and Protalix's pharmacovigilance responsibilities for the Licensed Product for pre-Launch Development activities in the Territory, and the process for exchanging adverse event reports and other safety information relating to a Licensed Product that will permit each Party to comply with applicable Laws and requirements of Regulatory Authorities (such agreement, the "Pharmacovigilance Agreement"); provided, that until such time as each of the Ongoing Clinical Trials and any [***] conducted by Protalix are completed, and the clinical study reports for each such clinical study are finalized, Protalix shall retain sole responsibility and be the primary contact for pharmacovigilance matters in respect of the Licensed Product.

(g) Communications with Regulatory Authorities.

(i) For so long as [***], Protalix, and after the assignment and transfer to Chiesi of such regulatory filings pursuant to Section 3.6(c), Chiesi, shall provide the other Party with notice of all meetings, conferences, and discussions (including advisory committee meetings or any other meeting of experts convened by a Regulatory Authority concerning any topic relevant to the Licensed Product) scheduled with a Regulatory Authority concerning any regulatory matters relating to the Licensed Product in the Field promptly after the scheduling of such meeting, conference, or discussion. The Party that does not, at the time of such meeting, own the regulatory filings described in Section 3.6(c) for the Licensed Product shall be entitled to have one or more representatives present at all such meetings to the extent permissible under applicable Law and reasonably practicable under the circumstances. Protalix and Chiesi 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 the applicable Regulatory Authority, if any [***].

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

(ii) For so long [***], Protalix, and after [***], Chiesi, shall provide the other Party with copies, which copies may be in draft form, of all material submissions to any Regulatory Authority in the Territory relating to the Licensed Product in the Field. Such copies shall be provided sufficiently in advance of such planned submission to the applicable Regulatory Authority in order to allow such other Party to provide comments regarding such submission. The Party making the submission shall consider the other Party's comments in good faith with respect to such submission [***].

(iii) Each Party shall provide to the other Party, as soon as reasonably practicable but in no event more than [***] after its receipt, copies of any material documents or other material correspondence received from a Regulatory Authority pertaining to the Licensed Product in the Field.

(h) Regulatory Information. Each Party agrees to provide the other with all reasonable assistance and take all actions reasonably requested by the other Party that are necessary or desirable to enable the other Party to comply with any Law applicable to the Licensed Product. For clarity, to the extent that either Party provides reasonably requested assistance to the other Party in compliance with this Section 3.6(h), the requesting Party shall reimburse such Party for any reasonable costs and expenses incurred in respect thereof.

(i) Recalls or Other Corrective Action. Each Party shall promptly notify the other Party of any material actions to be taken by such Party in the Territory or outside the Territory (as the case may be), with respect to any recall or market withdrawal or other corrective action related to the Licensed Product prior to such action, if reasonably practicable under the circumstances, to permit the other Party a reasonable opportunity to consult with such Party with respect thereto. [***].

(j) Ownership and Use of Clinical Data. Subject to Section 3.6(e), and subject to and solely to the extent expressly approved by the relevant IRB and permitted under applicable Law (and without violating the rights of any Third Party), all Clinical Data generated under this Agreement (solely in the Field and excluding (i) any regulatory filings submitted to any Governmental Authority, and (ii) rights in and to any Inventions or Patent Rights that arise out of or in relation to, or are otherwise embodied in, such data) shall be jointly owned by Protalix and Chiesi (the "Jointly Owned Clinical Data"), with each Party having an undivided one-half interest therein. If any such joint ownership cannot occur because such joint ownership is precluded by applicable Law, violates the rights of a Third Party or has not been expressly approved by the relevant IRB, the Party that owns such Clinical Data hereby grants the other Party a non-exclusive, perpetual, irrevocable, worldwide license to such Clinical Data, without any accounting to such Party, solely for use in a manner consistent with such Party's rights under this Agreement and the Ex-US Agreement (and, with respect to Chiesi as licensee, solely in the Field in the Territory). For the avoidance of doubt, the ownership rights to Jointly Owned Clinical Data provided for in this Section 3.6(j) shall not include or apply to any Inventions or Patent Rights that arise out of or in relation to, or are otherwise embodied in, any such Clinical Data (or the collection, generation or use thereof). For the avoidance of doubt, Chiesi's use of Jointly Owned Clinical Data is restricted to exercising its rights hereunder with respect to Licensed Product in the Field in the Territory and under the Ex-US Agreement with respect to Licensed Product in the Field outside the Territory.

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

3.7 Commercialization and Pricing.

(a) An initial draft Commercialization plan for the Licensed Product in the Field in the Territory prepared by Chiesi is attached as Schedule 3.7 hereto, and the final version of such Commercialization plan shall be discussed and agreed upon between the Parties within [***] after the Effective Date (the "Initial Commercialization Plan"). Chiesi shall update such plan (any such updated plan, the "Commercialization Plan") at least once per Calendar Year. Each such subsequent Commercialization Plan shall be submitted to the Steering Committee for review and discussion no later than thirty (30) days prior to the beginning of the immediately succeeding Calendar Year. Protalix may, through its representatives on the Steering Committee, propose to Chiesi revisions to any such subsequent Commercialization Plan, and any proposed material updates or amendments to the Initial Commercialization Plan and any subsequent Commercialization Plan, that Protalix reasonably believes are appropriate, and Chiesi shall consider any such proposed revisions in good faith, but such Initial Commercialization Plan or Commercialization Plan, or any material amendments or updates thereto, shall not require approval of the Steering Committee.

(b) Chiesi shall have the sole authority and exclusive right to Commercialize, and shall be responsible for paying all costs and expenses associated with the Commercialization of, the Licensed Product in the Field in the Territory, including marketing, promoting, advertising, distributing, disposing, offering for sale, selling, Labeling and Packaging, final product release testing, exporting and importing, and [***] in its sole discretion. Chiesi hereby agrees to refrain from selling the Licensed Product in the Territory to any Person if Chiesi has knowledge or reason to believe that such Licensed Product is intended for transshipment or delivery by such Person outside the Territory.

3.8 Early Access Programs. The Parties shall discuss at the Steering Committee the appropriate mechanism for considering, approving, providing for supply of Licensed Product in respect of, and otherwise administering, any Early Access Programs [***].

3.9 Trademarks.

(a) License to Chiesi. Protalix hereby grants to Chiesi an exclusive (except as to Protalix) license, free of charge, to use the Protalix Trademarks in the Territory (and, for so long as the Ex-US Agreement remains in effect, outside the Territory) solely in connection with the Commercialization of the Licensed Product in the Field during the Term in the Territory (and, for so long as the Ex-US Agreement remains in effect, outside the Territory), solely to the extent requested to be used by Protalix pursuant to, and solely for the purposes set forth in, Section 3.10. If Chiesi decides to use the Protalix Trademarks in the Territory or outside the Territory, then Chiesi shall cooperate with Protalix in respect of [***] recording the trademark license instrument with the appropriate Governmental Authorities.

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

(b) Choice of Trademarks. Chiesi may choose, in its sole discretion, to use any trademarks to Commercialize the Licensed Product in the Field in the Territory (and, for so long as the Ex-US Agreement remains in effect, outside the Territory), and Chiesi shall own all such trademarks, in accordance with the terms and conditions set forth in the Side Letter, other than the Protalix Trademarks or any other trademark owned or Controlled by Protalix at such time (such trademarks of Chiesi, the "Product Marks").

(c) Quality Control.

(i) The quality of the Licensed Product sold by Chiesi in the Territory and outside of the Territory under or in connection with the Protalix Trademarks must be of a sufficiently high quality (in the event of the expiration or termination of the Ex-US Agreement, to be generally comparable to the quality of any Licensed Product sold by Protalix outside of the Territory under or in connection with the Protalix Trademarks).

(ii) Chiesi shall comply with all applicable Laws pertaining to the proper use and designation of the Protalix Trademarks.

(iii) Chiesi agrees to use the Protalix Trademarks only in the form and manner and with appropriate legends as prescribed from time to time during the Term by Protalix.

(iv) Chiesi shall display the proper form of trademark notice associated with the Protalix Trademarks.

(v) Chiesi shall not use any Protalix Trademark as a corporate name, business name, or trade name.

(vi) Chiesi shall not use any Protalix Trademark in a manner that would reasonably be expected to materially impair the validity, reputation, or distinctiveness of any Protalix Trademark.

(vii) Chiesi shall not use any Protalix Trademark in a manner that would reasonably be expected to materially impair the reputation of Protalix or any of its Affiliates.

(d) Prosecution and Maintenance of Trademarks. Chiesi shall have the sole right, but not the obligation, through counsel of its choosing, to prosecute and maintain the Product Marks in the Territory and outside the Territory. [***] Protalix shall have the sole right, but not the obligation, through counsel of its choosing, to prosecute and maintain the Protalix Trademarks. [***].

(e) Enforcement of Trademarks. Each Party will promptly notify the other in the event of any actual, potential or suspected infringement of a Protalix Trademark or Product Mark by any Third Party. Chiesi 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 in the Territory and outside of the Territory. Any recoveries obtained by Chiesi resulting from such litigation or other appropriate action in the Territory and outside of the Territory in relation to the Product Marks, will be deemed Net Sales (under this Agreement or the Ex-US Agreement, as applicable) after having deducted any amount necessary to cover all costs and expenses incurred by Chiesi pursuant to the following sentence. All costs and expenses incurred by Chiesi in enforcing the Product Marks in the Territory and outside of the Territory shall be at Chiesi's sole cost and expense. 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 Trademarks. Upon request of Protalix, Chiesi agrees to timely join as party-plaintiff in any litigation in relation to the Protalix Trademarks, and in any event to cooperate with Protalix in connection with any infringement action in relation to the Protalix Trademarks, at Protalix's cost and expense. All costs and expenses incurred by Protalix in enforcing the Protalix Trademarks [***]. Protalix shall retain all recoveries received by Protalix as a result of its enforcement of the Protalix Trademarks. For so long as this Agreement remains in effect, this Section 3.9 hereby amends, replaces and supersedes in its entirety Section 3.9 of the Ex-US Agreement, which shall be of no further force or effect for so long as this Agreement remains in effect. In the event that the Ex-US Agreement expires or is terminated, then this Section 3.9 shall continue to apply, but solely in respect of the Territory.

3.10 Use of Names. No right, expressed or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name of the other Party or its Affiliates in connection with this Agreement. Notwithstanding the foregoing, Chiesi agrees, during the Term, to display the Protalix corporate name and logo (the "Protalix Trademarks") on the trade packaging used for the Licensed Product in the Field in the Territory in a reasonable manner (or as may be required under applicable Law), unless to do so would be prohibited under applicable Laws, or is not in accordance with the request of a Regulatory Authority, subject to Protalix's trademark usage guidelines applicable to the Protalix Trademarks provided from time to time during the Term, including at least sixty (60) days prior to the date of Chiesi's first use of the Protalix Trademarks. Upon the written request of Protalix, Chiesi shall submit to Protalix a sample of each proposed use of the Protalix Trademarks.

3.11 [***]

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

Section 4. MANUFACTURE AND SUPPLY.

4.1 Commercial Supply of Licensed Product.

(a) In respect of the Territory, other than to the extent this provision would be a violation of any applicable Laws in the Territory, Protalix shall Manufacture and supply, and Chiesi shall purchase from Protalix, all of Chiesi's and its Affiliates' requirements of the Drug Product (and, after [***]) for incorporation into Licensed Product for commercial sale in the Field in the Territory pursuant to and in accordance with this Agreement. Such supply shall be subject to and in accordance with the terms of this Section 4 and the Quality Agreement.

(b) Supply of Licensed Product for Extension Studies. To the extent that Chiesi conducts any Extension Studies, solely in respect of any quantities of Licensed Product required for the purposes of such studies, Protalix shall Manufacture and supply, and Chiesi shall purchase from Protalix, all of Chiesi's and its Affiliates' requirements of the Drug Product (and, after [***]) for the sole purposes of being administered to patients enrolled in such studies. Such supply shall be subject to and any accordance with the terms of this Section 4 and the Quality Agreement, except that the Price to be paid by Chiesi for such supply shall be equal to: (i) [***] per vial of [***] of Drug Product (or, after [***] per mg of Drug Substance) for all such supply used prior to the date of submission of the first regulatory filing for Regulatory Approval for the Licensed Product, or (ii) [***] per vial of [***] of Drug Product (or, after [***] per mg of Drug Substance) for all such supply used on or after the date of submission of the first regulatory filing for Regulatory Approval for the Licensed Product (in each case, shipping and delivery terms in respect of such purchased units shall be as otherwise set out in Section 4.7 below). For the avoidance of doubt, the Price paid by Chiesi in respect of such supply shall not be included in the Development Costs or [***] and shall not be subject to the cost-sharing arrangements, Development Costs Cap or Annual Cap set forth in this Agreement or the Ex-US Agreement. Chiesi shall keep and maintain records of (x) each delivery of Drug Product (and, after [***]) it receives in respect of supply for use in Extension Studies, and (y) the administration of such Licensed Product, on a patient-by-patient and site-by-site basis, in respect of such Extension Studies. Chiesi shall provide copies of the foregoing records to Protalix on a calendar quarterly basis (and otherwise on Protalix's reasonable request), together with a written report indicating then-current inventory levels of Drug Product (and, after [***]) intended for use in such Extension Studies.

4.2 [***].

4.3 Protalix Manufacturing Activities. Protalix shall have the sole authority and exclusive right for, and Protalix shall be responsible for, the Manufacture of Drug Product and, after [***].

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

4.4 Compliance of Third Parties. In the event that Protalix conducts any Manufacturing activities through an Affiliate or Third Party, Protalix shall be responsible for the performance of such Affiliate or Third Party in accordance with the terms of this Section 4. In the event that Chiesi conducts any Labeling and Packaging or, after [***] activities through an Affiliate or Third Party (such performance by an Affiliate or Third Party to comply with the terms of Section 2.4), Chiesi shall be responsible for the performance of such Affiliate or Third Party in accordance with the terms of this Section 4.

4.5 Forecasting and Ordering.

(a) Forecasts; Purchase Orders. [***], Chiesi shall deliver to Protalix Chiesi's quarterly projection of the quantities of Drug Product (or, after [***]) that Chiesi anticipates ordering from Protalix pursuant to this Agreement for the four (4) Commercial Quarters commencing with the first Commercial Quarter that includes the first requested delivery date (the "Initial Forecast"), together with a firm purchase order (a "Purchase Order") for such Drug Product (or, after [***]) for the first Commercial Quarter covered by such Initial Forecast and for at least [***] of the second Commercial Quarter covered by such Initial Forecast. The quantities of Drug Product (or, after [***]) specified for the following [***] of such Initial Forecast shall be non-binding. Thereafter, [***] prior to the first Business Day of each subsequent Commercial Quarter during the Term, Chiesi shall deliver to Protalix a rolling [***] Commercial Quarter forecast updating the prior forecast (together with the Initial Forecast, each a "Forecast"), together with a Purchase Order for such Drug Product (or, after [***]) for the first Commercial Quarter covered by such Forecast and for at least [***] of the second Commercial Quarter covered by such Forecast. The quantities of Drug Product (or, after [***]) specified for the following two (2) Commercial Quarters of such Forecast shall be non-binding. Unless agreed separately between the Parties, each Purchase Order shall (i) specify no more than one (1) delivery date for the Drug Product (or, after [***]) in each Commercial Quarter (unless each such delivery date in such Commercial Quarter is for a quantity of vials equal to the Minimum Batch Size or an exact multiple thereof), and (ii) be for a minimum quantity of the Minimum Batch Size. For the avoidance of doubt, for so long as this Agreement and the Ex-US Agreement are both in effect, the Minimum Batch Size shall apply on a combined basis with respect to unlabeled vials ordered and released in respect of anticipated sales in the Territory and outside of the Territory (i.e., Chiesi may split the ordered unlabeled vials included in the Minimum Batch Size (currently [***] vials) between amounts ordered for anticipated sales in the Territory and outside of the Territory, so long as such Purchase Order is for the Minimum Batch Size or an exact multiple thereof). Purchase Orders shall be in writing and no verbal communications or e-mail shall be construed to mean a commitment to purchase or sell. Each Purchase Order delivered by Chiesi to Protalix pursuant to this Section 4.5(a) shall be binding on Protalix, unless Protalix notifies Chiesi in writing of its rejection thereof within [***] of receipt of such Purchase Order; provided that Protalix may only reject Purchase Orders that do not comply with the terms of this Agreement or are otherwise not valid Purchase Orders (e.g., do not contain the requisite details).

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

(b) Long Range Capacity Planning. Concurrent with the Initial Forecast, for the purposes of discussion and planning of Manufacturing capacity, Chiesi shall provide a non-binding forecast of its projected Drug Product [***] needs for the [***] Commercial Quarters following that specified in the Initial Forecast as described in Section 4.5(a) (a "Long Range Forecast"). Each Long Range Forecast shall be deemed to be revised by any subsequent Forecast. In the event Protalix anticipates that it will be unable to supply the quantities of Drug Product [***] reflected in a Long Range Forecast, Protalix shall promptly notify Chiesi and the Parties shall work to remedy the shortfall in accordance with and subject to the terms of this Section 4 in an effort to assure that the necessary capacity exists. Unless otherwise agreed to by the Parties during the Term, the Long Range Forecast shall be updated by Chiesi annually by July 1 of each Commercial Year during the Term.

(c) Receipt and Acceptance. Chiesi shall purchase all Drug Product [***] ordered and specified in a Purchase Order. Purchase Orders may be delivered electronically or by other means to such location as Protalix shall designate. Nothing in any such Purchase Order or written acceptance shall supersede the terms and conditions of this Agreement or the Quality Agreement. All Purchase Orders, confirmations of receipt of Purchase Orders and other notices contemplated under this Section 4.5(c) 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 15.8.

(d) First-Expired First-Out. Chiesi shall use its inventory of Licensed Product, and any shipments of Drug Product [***], and each Party shall use its Safety Stock Amounts (as and when necessary), in each case, on a first-expired first-out (FEFO) basis in order to ensure that the Licensed Product in Chiesi's inventory (and the supply of Drug Product or, after [***], used in the production of such Licensed Product inventory) always has the maximum period of time remaining on the retest period.

4.6 Pricing, Invoicing and Supply Price Reconciliation.

(a) Supply Delivery Price; Invoices.

(i) Each delivery of Drug Product [***] under a Purchase Order hereunder shall be accompanied by an invoice. Protalix shall invoice such Drug Product [***] at the Price as at the date of such invoice. Chiesi shall issue payment against such invoices within [***] days of the invoice date. Protalix shall include the following information, where applicable, on all invoices: the type, description, and quantity of the product delivered; the date of shipment; the prices; any applicable taxes, transportation charges or other charges provided for in the applicable Purchase Order; and the applicable Purchase Order number.

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

(b) Taxes. All sales and use taxes which Protalix is required by applicable Law to collect from Chiesi with respect to the Manufacture and supply of Drug Product [***] to Chiesi shall be separately stated in Protalix's invoice and shall be paid by Chiesi to Protalix. For the avoidance of doubt, any and all applicable taxes shall be payable by Chiesi in addition to the Price payable on such Licensed Products. Protalix shall be solely responsible for the timely payment of all such taxes to the applicable taxing authority.

(c) Initial Price. Subject to the terms and conditions of this Agreement, before the start of the first Commercial Year in which Protalix is obligated to deliver Drug Product [***] pursuant to a Purchase Order issued by Chiesi, Protalix shall sell, and Chiesi shall purchase, the amount of Drug Product [***] ordered for delivery in the first Commercial Year at a Price determined by the Parties in good faith at least one Commercial Quarter prior to the anticipated start of the first Commercial Year in the Territory, reflecting [***] in the Territory.

(d) Ongoing Price. Subject to the terms and conditions of this Agreement, in any Commercial Year other than the first Commercial Year, Protalix shall sell, and Chiesi shall purchase, the amount of Drug Product [***] ordered for delivery in such Commercial Year at a Price equal to [***].

(e) [***]

(f) For the purposes of this Agreement, the "Applicable Rate" shall mean [***]:

Aggregate Annual Net Sales of Licensed Products	**Applicable Rates**
Less than [***]	[***]
Equal to or greater than [***] and less than [***]	[***]
Equal to or greater than [***] and less than [***]	[***]
Equal to or greater than [***] and less than [***]	[***]
Equal to or greater than [***] and less than [***]	[***]
Equal to or greater than [***]	[***]

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

(g) Quarterly Reconciliation. Notwithstanding the foregoing, in no event shall the Price paid by Chiesi for the Drug Product [***] ordered for delivery hereunder in any Commercial Quarter be less than [***]. If, at the end of a Commercial Quarter, the Price paid by Chiesi for the supply hereunder of Drug Product [***] during any Commercial Quarter is less than [***] in the aggregate, Chiesi shall pay Protalix the difference between such amounts against receipt of a proper invoice within [***] of the invoice date. For the avoidance of doubt, such amounts shall be in addition to (and in no way are intended to replace or subtract from) the amounts set forth in Section 4.6(g) of the Ex-US Agreement, which separately addresses the quarterly reconciliation of the Price paid for delivery under the Ex-US Agreement. In the event that the Ex-US Agreement expires or is terminated (other than termination by Chiesi for Protalix's material breach pursuant to and in accordance with Section 12.1(b) of the Ex-US Agreement), the references above to the minimum Price to be paid by Chiesi for the Drug Product [***] ordered for delivery hereunder in any Commercial Quarter shall be increased to [***], and such increase shall be effective in respect of both the Commercial Quarter in which such expiration or termination of the Ex-US Agreement occurred and any subsequent Commercial Quarters during the Term, until such time as Protalix enters into a new exclusive license agreement with a Third Party for the Commercialization of the Licensed Product in the Field in the territory (or substantially all of the territory) covered by the Ex-US Agreement.

(h) Yearly Reconciliation. The amounts due from Chiesi for Drug Product [***] ordered for delivery in each Commercial Year, as listed on the first invoice delivered to Chiesi for such Commercial Year, shall be increased or decreased, as the case may be, by the amount of a Reconciliation Adjustment aggregated in the Territory and meant to compensate in such Commercial Year for any inaccuracy in the Price paid in the Territory in the prior Commercial Year (the "Yearly Reconciliation"); provided that, notwithstanding anything to the contrary herein, in no event shall the amount due from Chiesi for the Drug Product [***] ordered for delivery in any Commercial Year be less than [***] in the aggregate for any Commercial Year (the "Minimum Payment"), subject to the potential pro-rata reduction of the Minimum Payment for failure to supply provided for in Section 4.14(f). For purposes of this Agreement, the "Reconciliation Adjustment" shall mean the aggregate in the Territory of the difference between:

(i) [***]; and,

(ii) [***].

Each Reconciliation Adjustment shall be settled against receipt of a proper credit note or debit note within [***] of the note date; provided that if any Reconciliation Amount is in the favor of Chiesi, such amounts shall be credited against the amount stated on the next issued invoice relating to the delivery of Drug Product [***] by Protalix to Chiesi under this Agreement. For the avoidance of doubt, such amounts shall be in addition to (and in no way are intended to replace or subtract from) the amounts set forth in Section 4.6(h) of the Ex-US Agreement, which separately addresses the yearly reconciliation of the Price paid for delivery under the Ex-US Agreement. In the event that the Ex-US Agreement expires or is terminated (other than termination by Chiesi for Protalix's material breach pursuant to and in accordance with Section 12.1(b) of the Ex-US Agreement), the references above to the Minimum Payment to be paid by Chiesi for the Drug Product [***] ordered for delivery in any Commercial Year shall be increased to [***] in the aggregate, and such increase shall be effective in respect of both the Commercial Year in which such expiration or termination of the Ex-US Agreement occurred and any subsequent Commercial Years during the Term, until such time as Protalix enters into a new exclusive license agreement with a Third Party for the Commercialization of the Licensed Product in the Field in the territory (or substantially all of the territory) covered by the Ex-US Agreement.

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

(i) Maximum Order Quantity. [***], the Parties shall agree in good faith on a maximum order quantity for the [***] and subsequent Commercial Years (the "Maximum Order Quantity"), expressed as a percentage above the amount of vials sold in the Territory in the prior Commercial Year [***] to mitigate the risk to Protalix of Chiesi ordering more Licensed Product than will be sold in such Commercial Year. If the Parties are unable to reach agreement on the Maximum Order Quantity in the Territory by [***], (i) the Parties shall attempt to reach an agreement by consensus through the Steering Committee, and (ii) if the Parties are still unable to reach an agreement within [***] of commencement of such Steering Committee discussions, the issue shall be escalated to the Parties' respective Chief Executive Officers, who shall attempt to resolve the issue within [***]. Notwithstanding anything to the contrary in this Agreement, Protalix shall have no obligation to supply Drug Product [***] in excess of the Maximum Order Quantity for the Territory.

(j) [***]

4.7 Shipping and Delivery.

(a) Delivery. Protalix shall deliver (or have delivered) to Chiesi in accordance with this Section 4.7 the quantities of the Drug Product [***] specified for a given delivery date in each Purchase Order [***]. Protalix shall deliver (or have delivered) (i) after [***] with a remaining shelf-life of [***], or (ii) prior to [***], with a remaining shelf life [***].

(b) Delivery Terms. The Drug Product [***] shall be supplied to Chiesi [***]. The Drug Product [***] shall be shipped at [***]. Chiesi shall be [***]. For the avoidance of doubt, Protalix shall be responsible for the importation of the Drug Substance in the EU with respect to the shipment of Drug Substance from Protalix to [***], and for compliance with all applicable Laws relating to such importation.

(c) Retention. Unless the Parties agree otherwise, Protalix shall maintain analytical samples of each batch of Drug Product (or, if necessary, Drug Substance) in storage for a time period based upon Protalix's sample retention policy.

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

4.8 Certificate of Analysis; Acceptance and Returns.

(a) Certificate of Analysis; Notice of Non-Conformance.

(i) Protalix shall supply to Chiesi the applicable batch number for the Drug Product [***] delivered, as well as such other information as the Parties may set forth in the Quality Agreement with respect to Manufacture (a "Manufacturing Certificate of Analysis") for all Drug Product [***] shipped to Chiesi hereunder. Chiesi shall (within the time period specified in Section 4.8(b)) inspect, or cause to have inspected, each shipment of the Drug Product [***] for any material damage, defect or shortage and give Protalix written notice of any such material damaged, defective or short shipment (a "Notice of Non-Conformance") within the time periods specified in Sections 4.8(a)(ii) and 4.8(b), as applicable.

(ii) Latent defects shall be communicated to Protalix, together with appropriate detail, within fifteen (15) Business Days of the date on which such latent defect was first discovered by Chiesi or was notified to Chiesi by the relevant Party discovering the defect.

(b) Rejection. Chiesi shall have [***] following its receipt of each shipment of the Drug Product [***] to inspect such shipment. If Chiesi determines that any shipment of the Drug Product [***] does not conform to the Product Specifications (or is otherwise a short shipment) in any material respect, it shall promptly notify Protalix within [***] following such determination in compliance with the procedures set forth in the Quality Agreement(s). Failure to provide such written notice with such time periods specified in Sections 4.8(a)(ii) and this 4.8(b), as applicable, shall be deemed acceptance of such shipment of Drug Product [***] by Chiesi.

(c) Disputes. If Chiesi delivers a Notice of Non-Conformance in respect of all or any part of a shipment of the Drug Product [***], and Protalix does not agree with Chiesi's determination that such shipment fails to meet the Product Specifications (or is otherwise a short shipment) in any material respect, the Parties shall in good faith attempt to resolve such dispute at the Steering Committee; provided, however, that the Steering Committee must resolve any such dispute by consensus, and for the avoidance of doubt, neither the Protalix Chair nor Chiesi Chair shall have final decision-making authority in respect of such Steering Committee discussions; provided, however, that for the duration of such Steering Committee discussions, Protalix shall use Commercially Reasonable Efforts to promptly replace such alleged non-conforming Drug Product [***] (or short shipment) in order to avoid any possible out-of-stock situation. The dispute shall be resolved at the Steering Committee within thirty (30) days, unless otherwise agreed in writing by the Parties, from the date of Protalix's receipt of a Notice of Non-Conformance to resolve such dispute regarding whether all or any part of such shipment was not Manufactured in conformance with the Product Specifications (or was otherwise a short shipment) in any material respect. If the dispute regarding whether all or any part of a shipment rejected by Chiesi was not Manufactured in conformance with the Product Specifications (or was otherwise a short shipment) in any material respect is not resolved by the Steering Committee in such thirty (30) day period, [***].

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

(d) Remedies. In the event any shipment of Drug Product [***] is rejected pursuant to this Section 4.8 as a result of any act or omission of Protalix, then (i) Chiesi shall, at the direction of Protalix, either (x) destroy such rejected Drug Product [***] (in accordance with applicable Law) or (y) return such rejected Drug Product [***] to Protalix, at a location designated by Protalix [***]; and (ii) Protalix [***] shall (in its sole discretion) either (x) use its Commercially Reasonable Efforts to promptly replace such non-conforming Drug Product [***] (or short shipment) or (y) give Chiesi a credit in an amount equal to the amount paid or payable by Chiesi with respect to such rejected Drug Product [***] (or short shipment).

4.9 Product Specification and Manufacturing Changes. Prior to the Parties entering into the Quality Agreement, Protalix shall inform Chiesi of material Product Specification and Manufacturing changes, including those resulting from a request received by Protalix from a Governmental Authority. Protalix shall notify Chiesi within a reasonable time prior to implementing such change, to allow Chiesi to assess the potential impact of such change upon the Drug Product supplied or its use by Chiesi and the implementation of such change shall not occur prior Chiesi's written approval (which approval shall not be unreasonably withheld, conditioned or delayed). After the Parties enter into the Quality Agreement, Product Specification and Manufacturing changes, including those resulting from a request received by either Party from a Governmental Authority, shall be dealt with pursuant to the Quality Agreement; provided that all applicable Regulatory Approvals shall be prepared and filed by the Parties in accordance with the provisions of Section 3.

4.10 Labeling. Chiesi shall be responsible for the design of the Label for the Licensed Product in the Territory and for ensuring that such Label is accurate and complies with all applicable Laws. Chiesi shall be responsible for obtaining approval from applicable Governmental Authorities for any new Label or packaging or change to Label or packaging and shall bear all costs arising therefrom, including in respect of any write-off of materials and work-in-progress unless otherwise included or required as part of the Development of the Licensed Product.

4.11 Shortages. In the event that the materials and/or Manufacturing capacity required to Manufacture and to deliver in a timely manner to Chiesi the Drug Product [***] required under outstanding Purchase Orders are in short supply ("Shortage"), Protalix shall notify Chiesi of such Shortage and the Steering Committee shall promptly meet to discuss the Shortage. Protalix shall provide to the Steering Committee a written plan of action stating in reasonable detail the proposed measures to address such Shortage and the date such Shortage is expected to end. Protalix shall use its Commercially Reasonable Efforts to minimize the duration of any Shortage. During any such Shortage, Protalix shall allocate the materials and resources used in the supply of the Drug Product [***] both in the Territory and outside the Territory, in such percentage proportions as determined by Chiesi in its sole discretion; provided that, in the event that the Ex-US Agreement expires or is terminated, the foregoing sentence shall not apply, and instead Chiesi shall be allocated [***] of such materials and resources for use in the supply of the Drug Product [***] for use in the Territory. For so long as this Agreement remains in effect, this Section 4.11 hereby amends, replaces and supersedes in its entirety Section 4.11 of the Ex-US Agreement, which shall be of no further force or effect for so long as this Agreement remains in effect.

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

4.12 Safety Stock Obligations

(a) Build-Up. [***], Protalix shall operate its Facility in order to start building inventory of [***], Drug Substance and Drug Product (the "Safety Stock") with the quantity of [***], Drug Substance and Drug Substance remaining after Protalix supplies the quantities of Drug Product and, if applicable, Drug Substance necessary to conduct the Ongoing Clinical Studies and any [***] and, after the Launch in the Territory, to meet commercial demand. Protalix shall operate its Facility in such manner until there is a quantity of Safety Stock consisting of (i) Drug Product capable of fulfilling the [***] commercial needs for Licensed Product in the Territory [***], based on the rolling Forecasts submitted by Chiesi pursuant to Section 4.5, (ii) Drug Substance capable of fulfilling the [***] commercial needs for Licensed Product in the Territory, based on the rolling Forecasts submitted by Chiesi pursuant to Section 4.5, and (iii) [***] capable of fulfilling the [***] commercial needs for Licensed Product in the Territory, based on the rolling Forecasts submitted by Chiesi pursuant to Section 4.5 (collectively, the "Safety Stock Amount"). Thereafter, subject to Section 4.12(b), Protalix shall operate its Facility as necessary to maintain the Safety Stock Amount. The Safety Stock may be used to fulfill Protalix's obligations to supply in the event there is a shortage as described in Section 4.11 or a Supply Failure (so long as such Safety Stock complies with the remaining shelf life required under Section 4.7(a), unless otherwise reasonably agreed by the Parties in a given circumstance); provided that [***] of such Safety Stock Amount shall be maintained for the exclusive use of Chiesi (i.e. [***]) in total, when taking into account the [***] provided for under Section 4.12(a) of the Ex-US Agreement).

(b) Sharing of Responsibility and Cost.

(i) For so long as subclause (x) of Section 4.6(h)(ii) applies in the Territory, (A) Chiesi shall bear the [***] responsibility for maintaining the Drug Product included in the Safety Stock Amount for the Territory through the inclusion of and payment for such Drug Product (as part of, and not in addition to) in applicable Purchase Orders placed in accordance with Section 4.5 and, for clarity, in the Yearly Reconciliation provided for under Section 4.6(h), and (B) Protalix shall bear the [***] responsibility for maintaining the Drug Substance included in the Safety Stock Amount in the Territory. On and from the date that such subclause (x) of Section 4.6(h)(ii) no longer applies in the Territory in accordance with such Section, the Parties shall share equally the responsibility [***] of building and maintaining the Safety Stock Amount for Drug Substance and Drug Product in the Territory, in a manner to be mutually agreed upon by the Parties in good faith at the same time the Maximum Order Quantity is agreed upon in accordance with Section 4.6(i) (and, for clarity, such Safety Stock Amount shall not be included in the Drug Product [***] ordered for the Territory for purposes of the Yearly Reconciliation). For clarity, following [***], Chiesi shall be solely responsible for the maintenance of any Safety Stock Amount of Drug Product [***]. Chiesi shall reimburse Protalix for its [***] share of the Safety Stock consisting of [***] within forty-five (45) days of Protalix providing Chiesi an invoice therefor.

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

(ii) The Forecasts and Purchase Orders submitted by Chiesi pursuant to Section 4.5 shall make a distinction between the amounts of Drug Product and Drug Substance required by Chiesi for commercial needs in the Territory and the amounts of Drug Product and Drug Substance needed for Safety Stock. For the avoidance of doubt, Protalix shall hold and keep the Safety Stock Amount of Drug Substance and, at Chiesi's option, Chiesi or [***] shall hold and keep the Safety Stock Amount (or a portion thereof) of Drug Product. Protalix shall, upon reasonable request and during regular business hours with as minimal disruption to Protalix's operations as reasonably practicable, allow Chiesi to audit the quantity of Safety Stock in Protalix's possession.

4.13 [***]

4.14 Failure to Supply.

(a) "Failure to Supply" shall occur in the event that Protalix does not supply according to the terms of this Agreement (to the Person responsible for [***]) for reasons within Protalix's reasonable control (and, for clarity, not for reasons outside Protalix's reasonable control, i.e., a Force Majeure Event) at least [***] of the quantities of Drug Substance specified by Chiesi on Purchase Orders covering [***] (a "Supply Failure"), and such Supply Failure is not cured in the following [***] period (whether by using Safety Stock or otherwise). For clarity, notwithstanding anything to the contrary herein, a failure to supply will not be treated as a Supply Failure under this Section 4.14(a) if such failure to supply was due to the failure to conduct [***] or Labeling and Packaging. For the sake of this Section 4.14(a), "cure" means supplying at least [***] of the quantities of Drug Substance specified by Chiesi on the applicable Purchase Orders that are the subject of the Supply Failure.

(b) Rights of Chiesi upon Failure to Supply. In the event of a Failure to Supply, at the option of Chiesi by giving written notice to Protalix, Chiesi shall have the right to, in compliance with applicable Laws and each Party's agreements with Third Parties, [***].

(c) Allocation of Costs. Protalix shall be responsible for [***]. This Section 4.14(c) hereby amends, replaces and supersedes in its entirety Section 4.14(c) of the Ex-US Agreement, which shall be of no further force or effect.

(d) Right of Protalix to Resume Manufacturing. Should Protalix provide Chiesi with commercially reasonable evidence that it is ready, willing and able, directly or through subcontractors reasonably acceptable to Chiesi, to resume its supply obligations hereunder, Chiesi and Protalix will work together in good faith to [***]; provided that notwithstanding anything to the contrary in this Agreement or the Ex-US Agreement, any exercise of this right or of the corollary right in Section 4.14(d) of the Ex-US Agreement, may only be exercised concurrently with such corollary right under the other agreement.

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

(e) [***]

(f) [***]

Section 5. FINANCIAL PROVISIONS

5.1 Effective Date Payment. In consideration for and as reimbursement of the costs sustained by Protalix up to the Effective Date for the Development of the Compound, Drug Substance, Drug Product and Licensed Product (such costs hereby acknowledged and accepted by Chiesi, without any right of further review, challenge or audit with respect to such costs) and in a manner consistent with Section 5.3(b) and Section 5.3(i), Chiesi shall pay to Protalix within twenty (20) days after the Effective Date, the non-refundable, non-creditable amount of Twenty-Five Million Dollars (US $25,000,000). For the avoidance of doubt, and notwithstanding the foregoing reference to Section 5.3(b), such amount shall not be included in or subject to the Development Costs Cap, Annual Cap, or any other cap on reimbursement provided for herein or in the Ex-US Agreement.

5.2 Event Milestone Payments.

(a) Subject to the terms and conditions of this Agreement, Chiesi shall pay to Protalix the amount set forth in the table below opposite the corresponding event milestone (each an "Event Milestone") within thirty (30) days after the occurrence of such Event Milestone:

Event Milestone	**Event Milestone Payment**
[***] ("Event Milestone 1")	[***]
[***] ("Event Milestone 2")	[***]
[***] ("Event Milestone 3")	[***]
[***] ("Event Milestone 4")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 5")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 6")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 7")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 8")	[***]

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

Event Milestone	Event Milestone Payment
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 9")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 10")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 11")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 12")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 13")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 14")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 15")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 16")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 17")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 18")	[***]
Annual Net Sales of the Licensed Product in the Territory equal to or in excess of [***] ("Event Milestone 19")	[***]

(b) [***]

(c) For the avoidance of doubt: (i) subject to Section 5.2(d) below, each Event Milestone Payment shall be payable only on the first occurrence of the corresponding Event Milestone; and (ii) none of the Event Milestone Payments shall be payable more than once.

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

(d) In respect of Event Milestones 5 through 19, should more than one Event Milestone occur in any Commercial Year, then only the highest of such Event Milestone Payments shall be due and payable in such Commercial Year (however, any Deferred Milestones may also be due and payable in such Commercial Year, subject to the below). For example, if Protalix achieves Event Milestone 5, Event Milestone 6, Event Milestone 7, and Event Milestone 8 in the first Commercial Year of this Agreement, only the Event Milestone Payment for Event Milestone 8 shall be due and the Event Milestone Payments for Event Milestone 5, Event Milestone 6 and Event Milestone 7 shall be deferred as set forth below and not paid in that Commercial Year (each, a "Deferred Milestone"). Such Deferred Milestones shall become due and payable in any subsequent Commercial Year in which the corresponding Event Milestone for each such Deferred Milestone is again achieved (irrespective of whether a higher Event Milestone is also achieved in such Commercial Year); provided, that the aggregate Net Sales for such subsequent Commercial Year have not decreased, as compared to the highest amount of Net Sales achieved in any previous Commercial Year. If the aggregate Net Sales for such subsequent Commercial Year has decreased, than only the highest Event Milestone achieved in such year will be payable (i.e., any unpaid Deferred Milestones again shall be deferred to the next Commercial Year). Following on from the above example, if in the subsequent Commercial Year Protalix achieves Event Milestone 5 and Event Milestone 6 only (meaning that there has been a decrease), then in such Commercial Year, the Deferred Milestone for Event Milestone 6 shall be due and payable (being the highest unpaid Event Milestone achieved in such Commercial Year), but the Deferred Milestone for Event Milestone 7 shall remain unpaid (as the corresponding Event Milestone was not achieved in that Commercial Year), and the Deferred Milestone for Event Milestone 5 shall also remain unpaid (as there was a decrease in Net Sales). If instead, the Net Sales increased (for example, Event Milestone 9 had been achieved), than each of the Deferred Milestones for Event Milestone 5, Event Milestone 6 and Event Milestone 7 will be due and payable in such Commercial Year (in addition to the Event Milestone Payment for Event Milestone 9). Following the above example, and assuming that in that second Commercial Year there had been a decrease in aggregate Net Sales, but that in the third Commercial Year, Protalix achieves each of Event Milestone 5, Event Milestone 6, Event Milestone 7, Event Milestone 8, and Event Milestone 9, then in such year, the Event Milestone Payment for Event Milestone 9 shall be due (as that is the highest of the Event Milestones achieved), as well as any unpaid Deferred Milestones (in the above example, the remaining Deferred Milestones would be Event Milestone 5 and Event Milestone 7).

(e) Protalix acknowledges and agrees that the right to receive Event Milestone Payments is not a security, shall not be represented by a certificate or other instrument and shall not represent a security or ownership interest in Chiesi, its Affiliates or any of their respective assets.

(f) NOTWITHSTANDING THIS SECTION 5.2, PROTALIX MAKES NO REPRESENTATION, WARRANTY OR COVENANT, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP AND CHIESI MAKES NO REPRESENTATION, WARRANTY OR COVENANT, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY COMMERCIALIZE THE LICENSED PRODUCT.

5.3 Development Costs.

(a) Development Costs in the Territory. The Parties acknowledge and agree that the provisions of this Section 5.3 regarding Development Costs are separate from, and in addition to, the provisions of Section 5.3 of the Ex-US Agreement regarding Development Costs. For the avoidance of doubt, the sharing of the Development Costs in the Territory, and the Development Costs Cap and Annual Cap, described in this Section 5.3 are each in addition to (and are in no way intended to replace or subtract from) the provisions governing the sharing of Development Costs, and the Development Costs Cap and Annual Cap, as provided in the Ex-US Agreement.

(b) Share of Costs. Subject to the Development Costs Cap and Annual Cap, and subject to Section 5.3(e), Chiesi shall reimburse Protalix for [***] of all Development Costs incurred on and after the Effective Date (i.e. totaling [***]of the total Development Costs, when taking into account the provisions of the Ex-US Agreement), within [***] of a receipt of an invoice therefor; provided that, until Regulatory Approval is obtained in the Territory for the Licensed Product, Chiesi may deduct from such reimbursable amounts payable to Protalix pursuant to this Section 5.3(b), [***] of any such amounts that comprise reimbursement hereunder for Development Costs that are indirect, internal costs of Protalix (e.g., Protalix employee hours).

(c) Development Costs Cap. Notwithstanding Section 5.3(b), if Chiesi's reimbursement obligation in respect of its share of the Development Costs under Section 5.3(b) at any point during the Term exceeds twenty million dollars (US$20,000,000) in the aggregate under this Agreement (i.e., totaling US$45,000,000 when taking into account the provisions of the Ex-US Agreement) during the Term (the "Development Costs Cap"), then Chiesi shall have the right but not the obligation to reimburse the amount exceeding the Development Costs Cap. If Chiesi decides to so reimburse, then Chiesi shall be entitled to credit any such amounts in excess of the Development Costs Cap that it pays to Protalix in accordance with Section 5.3(b) against the last invoice payment obligations of Chiesi to Protalix in respect of the Development Costs to be reimbursed by Chiesi as set forth under Sections 5.3(b) and 5.3(i). The reimbursement mechanism set forth under the previous sentence of this Section 5.3(c) hereby amends, replaces and supersedes the mechanism set forth in the last sentence of Section 5.3(b) of the Ex-US Agreement, which shall be of no further force or effect.

(d) Annual Cap. Notwithstanding Section 5.3(b), and subject to Section 5.3(c) above, Chiesi's reimbursement obligation in respect of its share of the Development Costs under Section 5.3(b) shall not, in any single Calendar Year during the Term, exceed seven million and five hundred thousand dollars (US$7,500,000) (the "Annual Cap") under this Agreement (i.e. totaling $17,500,000 when taking into account the provisions of the Ex-US Agreement); provided, however, that if in any Calendar Year during the Term Chiesi's reimbursement obligation in respect of its share of the Development Costs is less than the Annual Cap, the difference between Chiesi's actual reimbursement obligation for such Calendar Year and the Annual Cap for that Calendar Year shall carry forward to the next Calendar Year, such that the Annual Cap for that next Calendar Year shall increase by such amount (and in respect of such next Calendar Year, any references in this Agreement to Annual Cap shall be read as referring to such increased amount). If [***] of Development Costs for any Calendar Year exceeds the Annual Cap for that Calendar Year, then the difference between such actual Development Costs in that Calendar Year and the Annual Cap for such Calendar Year multiplied by 2.5 shall be deemed added to such Development Costs for the next Calendar Year (i.e., such amount will be subject to Chiesi's reimbursement obligation of [***] per Section 5.3(b) of such amount during the next Calendar Year, subject to the Annual Cap for such Calendar Year and the Development Costs Cap).

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

(e) [***]. In the event that either Party is obligated to undertake one or more [***] under the terms of this Agreement, subject to this Section 5.3(e), [***], in [***] of a receipt of an invoice therefor; [***]. For the avoidance of doubt, the [***] shall not in any event be included as a part of the Development Costs Cap or Annual Cap under Sections 5.3(c) and 5.3(d).

(f) Registry Costs. Notwithstanding anything to the contrary herein or in the Ex-US Agreement, Chiesi shall be responsible for maintaining the Registry (including the conduct of any post-Regulatory Approval obligations and fulfilling the requirements of any Regulatory Authority related thereto). For the avoidance of doubt, the Parties acknowledge and agree upon the desirability of maintaining one global Registry for both the Licensed Product in the Territory and outside the Territory. Chiesi shall be responsible for one hundred percent (100%) of the costs of the Registry.

(g) Clinical Studies Following Regulatory Approval and Additional Studies. Notwithstanding anything to the contrary herein but without prejudice to Sections 3.2(e) and 3.3(d)(iii): (i) Chiesi may only conduct Post-Approval Studies or Additional Studies (other than the Extension Studies) with the prior written consent of Protalix, such consent not to be unreasonably delayed, withheld or conditioned; and (ii) Chiesi shall be responsible for paying [***], and to the extent Protalix is required to (or is requested by Chiesi to) provide assistance in relation to the conduct of such Post-Approval Studies or Additional Studies, Chiesi shall [***] incurred in providing such assistance (and such reimbursement shall not be subject to the Development Costs Cap, Annual Cap, or any other cap on reimbursement provided for herein).

(h) Chiesi Step-in Rights. In the event that Chiesi exercises its step-in rights under Section 3.2(b) of this Agreement (or Section 3.2(b) of the Ex-US Agreement), and in the event that neither this Agreement nor the Ex-US Agreement have expired or been terminated, then each of Sections 5.3(a) through 5.3(d), as applicable, shall continue to apply with the obligation shifting to Protalix to reimburse Chiesi for [***] of all Development Costs for the Ongoing Clinical Studies incurred by Chiesi after the exercise of such step-in rights (i.e., replacing references to "Chiesi" with "Protalix" and vice-versa) in relation thereto, subject to the balances remaining under each of the Development Costs Cap and the Annual Cap, as applicable, as of the date on which Chiesi first exercises such step-in rights; provided that any such reimbursement obligation of Protalix shall not be required to be paid by Protalix, but rather shall only be applied by deducting such amounts from immediately applicable future payment obligations of Chiesi to Protalix under this Agreement or the Ex-US Agreement. For example, if one million dollars ($1,000,000) remains in the Development Costs Cap for the Ongoing Clinical Studies at the time Chiesi exercises its step-in rights, Protalix's responsibility to reimburse [***] of Chiesi's Development Costs in relation thereto shall be limited to a maximum of [***]. In the event that the remaining amount of the Development Costs Cap is exceeded during the course of Chiesi's exercise of its step-in rights, Chiesi shall be responsible for [***] of the Development Costs incurred in excess of such cap. [***]. For so long as this Agreement remains in effect, this Section 5.3(h) hereby amends, replaces and supersedes in its entirety Section 5.3(g) of the Ex-US Agreement, which shall be of no further force or effect for so long as this Agreement remains in effect. In the event that the Ex-US Agreement expires or is terminated, then this Section 5.3(h) shall continue to apply, but Protalix's obligation to reimburse Chiesi shall be for [***] of all Development Costs for the Ongoing Clinical Studies incurred by Chiesi after the exercise by Chiesi of such step-in rights (solely for the period after such expiration or termination of the Ex-US Agreement), and the examples set out herein shall be modified accordingly.

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

(i) Reimbursement Payments. Where either Party is required to reimburse the other Party in accordance with the terms of this Agreement (including, for the avoidance of doubt, if Protalix has incurred certain Development Costs but Chiesi is responsible for paying such Development Costs pursuant to this Section 5.3), then the Party to whom such reimbursement is owed (the "Reimbursed Party") may, on a monthly basis, send an invoice to such other Party (the "Reimbursing Party") with respect to such reimbursable amounts, along with reasonable evidence thereof (such evidence to consist of a report in substantially the form set out in Schedule 5.3(i), unless otherwise agreed in writing by the Parties), and such Reimbursing Party shall issue payment against such invoices within forty five (45) days of the invoice date (other than as set forth in this Section 5.3 or elsewhere in this Agreement, including Section 5.1). Without limiting the foregoing, in the event that a Governmental Authority responsible for the determination and collection of taxes conducts an audit of Chiesi and, in the course of such audit, requests certain back-up invoices, Protalix shall provide Chiesi with copies of such requested back-up invoices in Protalix's possession within five (5) Business Days of receiving notice of such Governmental Authority's request.

(j) CRO Agreements. Upon Chiesi's request, Protalix shall reasonably facilitate Chiesi being added as a party to Protalix's agreements with Third Parties that are contract research organizations performing Development services in respect of the Licensed Product in the Field (on terms agreeable to such Third Parties), for the primary purpose of enabling Chiesi to make direct payments of the costs of those Development services to such Third Parties (as opposed to Protalix making such payments and Chiesi reimbursing Protalix for Chiesi's share of such costs pursuant to Section 5.3); provided, however, that any such direct payments by Chiesi to such Third Parties shall be subject to (and shall count towards) (i) Chiesi's obligation to reimburse Protalix for Development Costs under Section 5.3(b) of this Agreement and Section 5.3(a) of the Ex-US Agreement, and (ii) the Development Costs Cap and Annual Cap as set forth in Sections 5.3(c) and 5.3(d) of this Agreement and Sections 5.3(b) and 5.3(c) of the Ex-US Agreement, in each case, in a manner that does not disadvantage either Party (i.e., with the intent of the Parties being that Chiesi's and Protalix's respective share of the Development Costs be economically the same whether Chiesi is paying such Third Parties directly or Protalix is paying such amounts to such Third Parties and being reimbursed by Chiesi in respect thereof pursuant to and in accordance with Section 5.3 of this Agreement and Section 5.3 of the Ex-US Agreement).

Section 6. ACCOUNTING AND PROCEDURES FOR PAYMENT

6.1 Periodic Reporting and Reconciliation Payments.

(a) Reports; Payments. Within [***], Chiesi shall provide Protalix with a report stating the Net Sales and computation thereof (including sales in units and in value of the Licensed Product made by or on behalf of Chiesi and its Affiliates in the Territory), and any permitted deductions from Net Sales, during such preceding Commercial Quarter, together with the calculation of the Price reconciliations as set out in Section 4.6(g) and, if applicable, Section 4.6(h) (together with any other supporting documentation reasonably requested by Protalix).

(b) Disputes. In the event of a dispute regarding any amount reported by a Party pursuant to Section 6.1(a), the disputing Party shall provide a notice of the dispute to the other Party, and the Parties will promptly meet and negotiate in good faith a resolution to such dispute. In the event that the Parties are unable to resolve such dispute within thirty (30) days after notice by the disputing Party, the Parties will (i) use Commercially Reasonable Efforts to reach agreement on the appointment of one internationally-recognized independent accounting firm to determine the matter, or (ii) if the Parties cannot reach agreement on such accounting firm within sixty (60) days after notice by the disputing Party, then each Party will appoint one internationally-recognized accounting firm and such firms will choose a third internationally-recognized independent accounting firm to make the final determination, which shall be binding on the Parties.

6.2 Currency. All payments to be made hereunder by one Party to the other Party shall be computed and paid in United States dollars.

6.3 Method of Payments. Each payment to be made hereunder by either Party to the other Party shall be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at the other Party's election, to the account designated (in writing) by the other Party on or before the Effective Date. With respect to any payment invoiced by either Party to the other Party, the other Party may designate a different bank account on such invoice. With respect to any other payment, either Party may designate a different bank account at least thirty (30) days before such payment is due.

6.4 No Set-Off. Except as otherwise expressly provided hereunder, all payments which either Party is required to make under this Agreement shall be made without any set-off, counterclaim or condition.

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

6.5 Interest for Late Payments. If either Party fails to make any payment due under this Agreement within [***] of the date upon which such payment is due, then interest shall accrue on such payment on a daily basis from the date such payment was originally due at a rate equal to weekly LIBOR (as published in The Wall Street Journal, New York edition and as officially confirmed by an officer of the respective Party) plus [***], or at the maximum rate permitted by applicable Law, whichever is the lower, and such interest shall be paid when such payment is made.

6.6 Inspection of Records. Chiesi shall, and shall cause its Affiliates to, keep accurate books and records with respect to the Commercialization of Licensed Product hereunder, setting forth gross sales of the Licensed Product and Net Sales sufficient to enable the calculation of amounts payable hereunder to be verified. Protalix shall, and shall cause its Affiliates and sublicensees to, keep accurate books and records setting forth the Price for the Licensed Products purchased by Chiesi from Protalix hereunder, sufficient to enable the calculation of the Price to be verified (the foregoing books and records of Chiesi and Protalix and their respective Affiliates and sublicensees, the "Financial Records"). Additionally, each Party shall keep sufficiently detailed books and records to enable the other Party to monitor such Party's compliance with the provisions of Sections 9.1(i) and 9.1(j) below (such additional books and records, "Compliance Records"). Each Party will retain such Financial Records and Compliance Records for [***] after the end of the Calendar Year, in which they are generated in order to enable audit of such records as set forth below. Each Party will have the right to request that an independent certified public accountant selected by it examine the other Party's Financial Records, or that such Party's nominated representative examine the other Party's Compliance Records, in each case, at any reasonable time, upon reasonable notice and at the facility(ies) where the other Party's Financial Records or Compliance Records are normally kept (an "Audit"). The foregoing rights of examination may be exercised only [***] during each twelve (12)-month period of the Term and only [***] during each twelve (12)-month period in the three (3) years after final payment has been made. The audited Party may require such accountants (or nominated representative) to enter into a reasonably acceptable confidentiality agreement. In respect of an Audit of a Party's Financial Records, the opinion of said independent accountants regarding such payments shall be binding on the Parties, other than in the case of manifest error. Except as set forth below, [***] shall bear the cost of any such examination and review. In respect of a Party's Financial Records, if such Audit by either Party of the other Party's books and records reveals that such other Party has made an underpayment (or received an overpayment) under this Agreement, then the Party in receipt of any such overpayment, or the Party responsible for any such underpayment, shall promptly reimburse the other Party in the amount of such overpayment or underpayment (as applicable) as was revealed by such Audit. If the discrepancy revealed by the Audit is greater than [***] of the amount due, then the Party responsible for the inaccurate reporting resulting in such overpayment or underpayment shall also promptly reimburse the other Party for any and all costs incurred in connection with such Audit.

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

6.7 Tax Matters.

(a) Taxes. Subject to Section 6.7(c) below, Chiesi shall assume and pay any and all taxes, customs, duties, assessments, excises and other charges levied upon the importation of or assessed against the Drug Product [***] supplied or rights licensed by Protalix hereunder, or for or on account of the Commercialization of the Licensed Product in the Territory. Prior to [***], Protalix shall assume and pay any and all taxes, customs, duties, assessments, excises and other charges levied upon the importation of or assessed against the Drug Substance in the EU with respect to the shipment of Drug Substance from Protalix to [***].

(b) VAT. It is understood and agreed between the Parties that any payments made by Chiesi under this Agreement are exclusive of any value added or similar tax imposed upon such payments.

(c) Withholding Tax. Payments made by Chiesi to Protalix pursuant to this Agreement shall be made free and clear of any withholding in respect of taxes. [***]. Section 6.7(c) of the Ex-US Agreement is hereby amended to add the words "or Section 5.3" following the words "Section 5.1" in the first sentence of such Section 6.7(c) of the Ex-US Agreement.

(d) Cooperation. Each Party shall provide the other with reasonable assistance to enable a reduction in, elimination of, or the recovery, as permitted by applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT. Chiesi shall provide reasonable notice to Protalix of its intent to withhold any amount in respect of taxes, and Protalix shall provide to Chiesi any tax forms that may be reasonably requested by and necessary for Chiesi not to withhold tax or to withhold tax at a reduced rate under applicable Law (including an applicable income tax treaty). 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 Chiesi to Protalix under this Agreement. Chiesi assumes the sole responsibility of procuring any required permits, authorizations, licenses or consents of Governmental Authorities 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 applicable Law, such "blocked" funds shall be deposited to the credit of Protalix in such depository as Protalix designates subject to such applicable Law or Chiesi or its Affiliates shall otherwise pay Protalix an amount equal to such "blocked" funds.

Section 7. PATENTS AND INFRINGEMENT

7.1 Filing and Prosecution.

(a) Except as set forth in Section 7.1(b), Protalix shall have the exclusive right, subject to Sections 7.2 through 7.5, to:

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

(i) file Patent Applications on any Invention included in the Protalix Patent Rights or otherwise arising from the collection, generation or use of Clinical Data or its performance of Development activities under this Agreement;

(ii) take all reasonable steps to prosecute all pending and new Patent Applications included within the Protalix Patent Rights;

(iii) maintain in force any patents in the Territory included within the Protalix Patent Rights by duly filing all necessary papers and paying any fees required by the relevant patent Laws of the United States.

[***].

(b) With respect to the Patent Applications set forth on Schedule 7.1(b) and any future Patent Applications covering the Compound or Licensed Product in the Field in the Territory claiming priority to, or common priority with, the Patent Applications set forth on Schedule 7.1(b) (in each case, solely to the extent not related to the System), Chiesi shall have the option, upon thirty (30) days' notice to Protalix, to take over the prosecution and maintenance of any or all of such Patent Applications (which shall remain in Protalix's name), including the sole right to file new Patent Applications in Protalix's name covering the Compound or Licensed Product in the Field in the Territory. [***]. Chiesi will notify Protalix of any decision to cease prosecution and/or maintenance of any of such Patent Applications (or resulting Patents) for which it opts to take over the prosecution and maintenance pursuant to this Section 7.1(b), or not to pursue, or to cease to [***], any such Patent Applications or resulting Patents. In such event, Protalix shall have the right to make the filing, or to continue and take back control over the prosecution and maintenance of such Patent Rights.

7.2 Correspondence.

(a) Protalix will keep Chiesi informed of the status of the Protalix Patent Rights to the extent the Protalix Patent Rights [***].

(b) Protalix will, upon Chiesi's request, provide Chiesi with copies of all substantive documentation submitted to, or received from, the United States Patent and Trademark Office in connection therewith. With respect to any Protalix Patent Rights that are not Protalix System Patent Rights, Protalix shall consider in good faith all comments provided by Chiesi with respect to a Protalix Patent Right in the Territory to the extent relating to the Compound or Licensed Product and/or other recombinant form of alpha Galactosidase in the Field in the Territory or the Commercialization of the Licensed Product in the Field in the Territory. Protalix shall have final-decision making authority with respect to filings and prosecution of Protalix Patent Rights.

(c) Notwithstanding anything to the contrary in this Agreement, Chiesi shall have the sole right in electing which Patent shall receive any patent term extension under 35 U.S.C. § 156 related to the Licensed Product in the Territory. Protalix and Chiesi shall cooperate in timely filing and obtaining the patent term extension for such Patent elected by Chiesi.

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

7.3 Maintenance. Protalix will use [***] to maintain for the full life thereof all Patent Rights under the Protalix Patent Rights where the abandonment for non-payment [***]. Protalix will notify Chiesi of any decision (a) not to file a Patent Application for, or (b) not to enter the national phase for a PCT Patent Application for, or (c) to cease prosecution and/or maintenance (including the occurrences as set out in Section 7.2) of, or (d) not to pursue, or (e) to cease to pay the expenses of prosecution or maintenance of, any Protalix Patent Rights in the Field in the Territory. In such event, Chiesi shall have the right to make the filing, or to continue the prosecution and maintenance of such Patent Rights (other than Protalix System Patent Rights) in Protalix's name [***]. Notwithstanding the foregoing, Protalix shall have no obligation to provide such notice where the subject Protalix Patent Rights are directed [***].

7.4 Notices. Protalix agrees that it will, and will cause its Affiliates to execute and file those notices and other filings as Chiesi shall reasonably request be made, from time to time with the United States Patent and Trademark Office with respect to the rights granted under this Agreement, at Chiesi's sole cost and expense.

7.5 Interpretation of Patent Judgments. If any claim relating to a Patent under the Protalix Patent Rights becomes the subject of a judgment, decree or decision of a court, tribunal, or other authority of competent jurisdiction in the Territory, which judgment, decree, or decision is or becomes final (there being no further right of review) and adjudicates the validity, enforceability, scope, or infringement of the same, the construction of such claim in such judgment, decree or decision shall be followed thereafter in the Territory not only as to such claim but also as to all other claims in the Territory to which such construction reasonably applies, in determining whether there are any Valid Claims in the Territory. If at any time there are two or more conflicting final judgments, decrees, or decisions with respect to the same claim, the decision of the higher tribunal shall thereafter control, but if the tribunal be of equal rank, then the final judgment, decree, or decision more favorable to such claim shall control unless and until the majority of such tribunals of equal rank adopt or follow a less favorable final judgment, decree, or decision, in which event the latter shall control.

7.6 Third Party Royalty Obligations.

(a) If either Party reasonably determines in good faith that in order to avoid infringement of any Patent Right not licensed hereunder, it is reasonably necessary to obtain a license or acquire the relevant Patent Right or Technology from a Third Party in order to make, use, sell, offer for sale, supply, cause to be supplied, or import the Licensed Product in the Territory and to pay a royalty or other consideration under such license or acquisition (including in connection with the settlement of a patent infringement claim), then the Steering Committee shall discuss the pertinent Third Party Patent Right and/or Technology and such Party's determination. If the Steering Committee decides (by mutual agreement of the Steering Committee members) that Chiesi should enter into such license or acquisition, whether as part of a settlement of an allegation or claim of infringement of a Third Party Patent or otherwise, Chiesi shall use Commercially Reasonable Efforts to negotiate and enter into a license or acquisition for such Third Party Patent Right and/or Technology and the Steering Committee (by mutual agreement of the Steering Committee members) shall determine each Party's respective share of any payments to the relevant Third Party, other than as provided in Section 13.2. If the Steering Committee is unable to decide (by mutual agreement of the Steering Committee members) whether Chiesi should enter into such a license or acquisition, whether as part of a settlement of an allegation or claim of infringement of a Third Party Patent or otherwise, and Chiesi enters into a license or acquisition for such Third Party Patent Right and/or Technology in good faith on arms-length terms, Protalix's share of any payments to the relevant Third Party, other than as provided in Section 13.2, shall be equal to [***] of the Applicable Rate in effect at the time Chiesi enters into such agreement; provided, that if (i) Chiesi enters into any such agreement with respect to an infringement (or possible infringement) occurring within eighteen (18) months of the receipt of Regulatory Approval for the Licensed Product in the Territory; (ii) the Third Party Patent Right being licensed or acquired is a Competing Product Patent; and (iii) the Event Milestone 2 has been paid, or is payable, to Protalix, then Protalix shall be responsible for [***] of any such payments due to any such Third Parties in respect of any such licenses or acquisitions, up until Protalix's responsibility reaches [***] in the aggregate, with any remaining payments due to any such Third Parties in respect of any such licenses or acquisitions being shared by the Parties, with Protalix's share of any such remaining payments being equal to the Applicable Rate in effect at the time Chiesi enters into such agreement. To the extent this Section 7.6(a) provides for any costs or expenses to be shared between the Parties, Protalix's share of such costs and expenses are only to be deducted from future payment obligations of Chiesi to Protalix under this Agreement (and, for clarity, shall not otherwise be separately payable by Protalix).

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

(b) Other than as provided in Section 13.2, if Chiesi is subject to a final court or other binding order or ruling requiring any payments, including the payment of a royalty to a Third Party Patent holder in respect of Commercialization of the Licensed Product in the Territory, then the amount of such payments made by Chiesi to the Third Party shall be in addition to, and separate from, any payments due to Protalix under this Agreement; provided that the Steering Committee (by mutual agreement of the Steering Committee members) shall determine each Party's respective share of any such payments to the relevant Third Party; provided further that if (i) such final court or other binding order or ruling is made with respect to an infringement occurring within eighteen (18) months of the receipt of Regulatory Approval for the Licensed Product in the Territory; (ii) the required payments are with respect to a Competing Product Patent; and (iii) the Event Milestone 2 has been paid, or is payable, to Protalix, then Protalix shall be responsible for [***] of any such payments to any such Third Parties, up until Protalix's responsibility reaches [***] in the aggregate, with any remaining required payments due any such Third Parties being shared by the Parties, with Protalix's share of any such remaining payments being equal to the Applicable Rate in effect at the time of the final court or other binding order or ruling. To the extent this Section 7.6(b) provides for any costs or expenses to be shared between the Parties, Protalix's share of such costs and expenses are only to be deducted from future payment obligations of Chiesi to Protalix under this Agreement (and, for clarity, shall not otherwise be separately payable by Protalix). For clarity, the reference to the [***] under the foregoing proviso and under the proviso in the last sentence of Section 7.6(a) shall be an aggregated amount, such that if Protalix's responsibility reaches) under either proviso, it should not have an obligation to share [***] under the other proviso (e.g., if Protalix's responsibility has already reached [***] under the proviso in the last sentence of Section 7.6(a), then the [***] threshold will have been deemed to already be reached and Protalix's share of the responsibility under the proviso in this Section 7.6(b) would thus be equal to the Applicable Rate then in effect).

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

7.7 Third-Party Infringement. Each Party will promptly notify the other in the event of any actual, potential or suspected infringement of a Patent under the Protalix Patent Rights by any Third Party.

(a) Infringement of Protalix Patent Rights in the Field.

(i) Chiesi shall have the sole right, but not the obligation, to institute litigation or take other remedial measures in connection with Third Party infringement of the Protalix Patent Rights occurring in the Field within or for the Territory, including, without limitation, any [***] in or for the Territory (other than Protalix Patent Rights directed solely to an Outside of the Scope Product). Protalix, upon request of Chiesi, agrees to timely commence or to join in any such litigation [***], and in any event to reasonably cooperate with Chiesi [***]. Any costs and expenses incurred by Chiesi with respect to any such litigation or remedial measures shall be borne by Chiesi, and any recoveries resulting from such litigation or measures relating to a claim of a Third Party infringement in pursuing such claim, will be deemed Net Sales after having deducted any amount necessary to cover all costs and expenses incurred by Chiesi pursuant to the preceding sentence. With respect to any [***] in or for the Territory, Chiesi shall have sole control of, and decision making authority with respect to, the communications, exchange of information, procedures and actions set forth or described in [***]; provided, however, that, prior to engaging in any of the foregoing acts or exercising such decision-making authority, Chiesi shall provide written notice to Protalix thereof and consult and cooperate in good faith with Protalix with respect thereto (including considering any suggestions made by Protalix in respect thereof in good faith).

(ii) Chiesi shall have sole authority to settle any litigation, action or proceeding brought by Chiesi pursuant to Section 7.7(a)(i), provided that Chiesi shall not effect any settlement of any litigation, action or proceeding in which Protalix has any potential liability, unless such settlement involves solely monetary damages for which Protalix is not responsible and includes an unconditional release of Protalix for all liability on Claims that are the subject matter of such litigation, action or proceeding.

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

(iii) 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 any Protalix Patent Rights directed solely to any Outside of the Scope Product or occurring outside the Field (within or outside of the Territory) [***].

7.8 Other Actions by a Third Party.

(a) Each Party shall promptly notify the other in the event of any (i) claims by a Third Party of alleged patent infringement by Chiesi or Protalix or any of their respective Affiliates with respect to the research, Development, Manufacture, use, sale, offer for sale or importation of a Compound (other than as used in New Use) or the Licensed Product, in each case, in the Field in the Territory or (ii) legal or administrative action by any Third Party involving a Protalix Patent Right in the Field in the Territory [***] of which it becomes aware, including any petition for ex parte reexamination, Inter Partes Review (IPR), or Post Grant Review (PGR), nullity, revocation, reexamination or compulsory license proceeding. Unless subject to the indemnity provided by Protalix under Section 13.2 (in which case Protalix shall have sole control of such action and the defense thereof as provided under Section 13.2) or for a Third Party Claim for which Chiesi irrevocably waives Protalix's obligation to indemnify Chiesi under Section 13.2, Chiesi shall have the first right, but no obligation, to defend against any such action involving such alleged infringement or such Protalix Patent Right, in each case, in the Field in the Territory [***]; provided, that if the action involves an assertion that a Competing Product Patent is, or would be, infringed by the Compound (other than as used in a New Use) or the Licensed Product, in each case, in the Field in the Territory, Protalix shall be [***]. Without prejudice to the foregoing proviso, Protalix, upon request of Chiesi, agrees to join in any such action [***] and in any event to reasonably cooperate with Chiesi [***]. If Chiesi declines to defend against any such action involving the Compound (other than as used in New Use) or the Licensed Product or a Protalix Patent Right, then Protalix shall have the right to defend such action [***]. Chiesi, upon request of Protalix, shall reasonably cooperate with Protalix in any such action [***]. The Party defending against such action in accordance with this Section 7.8 shall assume direction and control of the defense, litigation, settlement, appeal or other disposition of such Claim (including the right to settle the Claim solely for monetary consideration for which such Party will be responsible) with counsel selected by such Party and reasonably acceptable to the other Party. The other Party shall have the right to reasonably participate in (including the right to participate in all settlement conferences and provide suggestions, which the controlling Party shall consider in good faith), but not control, at its own expense, the defense of any Claim that such Party is defending as provided in this Section 7.8.

(b) In the event an injunction is entered against Chiesi or Chiesi is otherwise enjoined by a court of competent jurisdiction from Commercializing the Licensed Product in the Territory based on a claim that the Compound or Licensed Product infringes, or would infringe, a Third Party's Patent, until such injunction is lifted or such binding order or ruling is overturned, (i) Chiesi may cancel or suspend any outstanding Purchase Orders for the Territory and its ordering and forecasting obligations under this Agreement (provided that Chiesi ceases any ordering hereunder), and shall not be obligated to make the Minimum Payment hereunder, (ii) Protalix's obligations under Sections 4.11 and 4.12 shall cease (in each case, solely in respect of the Territory), and (iii) Chiesi shall use Commercially Reasonable Efforts to seek to promptly have such injunction lifted or such binding order or ruling overturned.

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

(c) With respect to any action brought pursuant to Section 7.8, neither Party will enter into any settlement of any suit involving Licensed Products that materially affects the other Party's rights or obligations with respect to the Licensed Product without the other Party's prior written consent (which consent shall not be unreasonably withheld, delayed or conditioned). Without limiting the foregoing, neither Party shall, without the written consent of the other Party (which consent shall not be unreasonably withheld, delayed or conditioned), effect any settlement of any pending or threatened litigation in which the other Party has any potential liability, unless such settlement involves solely monetary damages and includes an unconditional release of such other Party from all liability on Claims that are the subject matter of such litigation.

7.9 Patent Marking. Each Party shall comply with the patent marking statutes in the Territory in which a Licensed Product in the Field is made, offered for sale, sold or imported by such Party and its Affiliates and sublicensees.

Section 8. CONFIDENTIALITY; PUBLICATION

8.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, the Parties agree that for the Term and for [***] years thereafter, each Party shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose any Confidential Information furnished to it by the other Party pursuant to this Agreement, in a manner no less protective than the actions it would customarily take to preserve the confidentiality of its own similar types of confidential information.

8.2 Permitted Disclosures. Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information (a) to such Party's employees, consultants (including, for greater certainty, financial advisors), Affiliates, agents, contractors, or permitted sublicensees who are bound by obligations relating to confidentiality at least as restrictive of those contained herein and who have a need to know such information in connection with such Party's performance of its obligations or practice or enforcement of its rights under this Agreement, (b) to Regulatory Authorities in connection with any Regulatory Approvals required for Development of Licensed Product pursuant to the Development Plan or in compliance with applicable Law, including any requirements under or pursuant to the Food and Drug Administration Amendments Act of 2007, or (c) pursuant to Sections 8.3 and 8.4.

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

8.3 Terms of Agreement. The Parties agree that the material terms of this Agreement will be considered Confidential Information of both Parties. Subject to Section 8.4 below, no Party shall, without the prior written consent of the other Party, disclose in any manner to any Third Party the material terms and conditions of this Agreement, except for terms or subject matter which has been the subject of prior public disclosure or has been mutually approved for such disclosure and except as set forth below. Chiesi acknowledges that Protalix or its Affiliates may be legally required to file this Agreement as an exhibit to filings with the U.S. Securities and Exchange Commission. In addition: (a) either Party may disclose such terms as are required to be disclosed in its publicly-filed financial statements or other public statements, pursuant to applicable Laws, regulations and stock exchange rules (e.g., the rules of the U.S. Securities and Exchange Commission, the NYSE American, the NYSE, NASDAQ, or any other stock exchange on which securities issued by either Party may be listed); provided that such Party shall provide the other Party with a copy of the proposed text of such statements or disclosure (including any exhibits containing this Agreement) sufficiently in advance of the scheduled release or publication thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text (including redacted versions of this Agreement), (b) either Party shall have the further right to disclose the terms of this Agreement under a confidentiality obligation no less protective than those set forth in this Agreement, to any potential sublicensee, acquirer, merger partner, investor, business partner or potential providers of financing and their advisors or, in the case of Protalix, to the owner of any Protalix Patent Rights or Protalix Technology Controlled by Protalix, and (c) Protalix and Chiesi shall have the right to disclose information regarding the development or commercialization status of the Licensed Product in the Field in the Territory to the extent such disclosure by Protalix or Chiesi, as applicable, is required by applicable Laws or stock exchange rules.

8.4 Mandatory Disclosure.

(a) Notification and Consultation. In the event that a Party is required by applicable Law (including rules of an applicable stock exchange), or pursuant to legal, governmental or self-regulatory organization proceedings (including by court order or judicial or administrative process) to disclose any part of the other Party's Confidential Information (including material terms or conditions of this Agreement), such Party shall (i) promptly notify the other Party of each such requirement and identify the documents so required thereby, so that the other Party may seek an appropriate protective order, confidential treatment or other remedy concerning any such disclosure and/or waive compliance by such Party with the provisions of this Agreement and (ii) consult with the other Party with respect to taking legally available steps to resist or narrow the scope of such requirement.

(b) Limited Disclosure. If, in the absence of such a protective order, confidential treatment request, other remedy or waiver by the other Party, such Party is nonetheless required to disclose any part of the other Party's Confidential Information or any material terms or conditions of this Agreement, such Party may disclose such Confidential Information or material terms or conditions without liability under this Agreement, except that such Party shall furnish only that portion of the Confidential Information or material terms or conditions that in its good faith judgment, after consultation with legal counsel, it is legally required to provide.

8.5 Publication. Subject to the restrictions set out below, nothing herein shall prevent Protalix and its Affiliates (and their respective employees, consultants, contractors, licensees and agents) from publishing or presenting information relating to the development or use of the System, Compound or Licensed Product or otherwise (a) limit the rights of Protalix's Third Party clinical investigators to publish the results of their studies or (b) prevent Protalix or its Affiliates from complying with applicable Law with respect to the disclosure of clinical study data and results or of any other material matter or information. Each Party recognizes that the publications regarding results of and other information regarding Development of Licensed Products in the Field in the Territory, including oral presentations and abstracts, may be beneficial to both Parties, provided that publications are subject to reasonable controls to protect Confidential Information and the Parties' mutual interest in obtaining rights in patent and protecting trade secret information. The Steering Committee shall appoint one referent person for each Party for reviewing and approving such publications ("Referent Person"). Accordingly, the Party proposing to submit any such publication or presentation shall first deliver to the Referent Person for review a copy of such Party's proposed publication or presentation that pertains to the Compound, Drug Substance, Drug Product or Licensed Product in the Field in the Territory prior to submitting the material to a publisher or initiating any such publication thereof. The Referent Person of the non-proposing Party must make a reasonable, good faith determination as to (solely in respect of publications to scientific journals or similar mediums and submission of abstracts to medical congresses) whether the proposing Party may submit such publication, and may (x) require modifications of such publication prior to it being submitted (i) to protect each Party's respective Confidential Information, or (ii) for trade secret reasons or other material commercial reasons; (y) request that the proposing Party delay such submission for an additional period as may be reasonably necessary to seek patent protection for the information disclosed in such proposed written submission; and (z) withhold its approval for such publication if it makes a reasonable, good faith determination that such publication will have an adverse effect on the non-publishing Party's ability to procure a patent or Develop or Commercialize any Licensed Product. The Referent Person of the non-publishing Party shall conduct its review and provide its approval as promptly as reasonably practicable, but in any event within [***] days in case of publications to scientific journals or similar medium and any abstracts to medical congresses (and the failure to provide any such response with such [***] day period shall be deemed approval hereunder). If the Parties are unable to reach agreement on whether the proposing Party may submit such publication, or on the scope of any reasonably necessary modifications or delay in respect of such publication, the issue shall be escalated to the Parties' respective Chief Executive Officers, who shall attempt to resolve the issue within [***] days. In respect of any oral or in-person presentations at medical conferences or medical congresses, posters, trade shows, or similar activities (but, for clarity, excluding business forums), the Referent Person of the non-publishing Party shall be afforded at least [***] Business Days to review and provide comment on any initial working draft thereto and [***] Business Days to review and provide comment on any revised draft (unless a working draft or revised draft is not available or, acting in good faith, the publishing Party considers such review period would risk delaying submission or missing a relevant deadline), and the publishing Party shall consider any such comments received during such [***] Business Day period in good faith; provided, however, that in respect of such oral or in-person presentations, the publishing Party shall not require the approval of the Referent Person of the non-publishing Party to proceed with such presentation.

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

8.6 Publicity. A draft public announcement of the execution of this Agreement is set forth on Exhibit C attached hereto and, subject to Protalix's further review and comment, shall be promptly disseminated as a press release following the execution of this Agreement by both Parties and the approval by Protalix of the final form thereof. Other than with respect to the matters addressed in Section 8.5 and disclosures required by applicable Law or stock exchange rules, each Party shall only issue press releases that contain material new information (i.e., material information that has not been previously disclosed) concerning the terms of, or events related to, this Agreement or concerning the Compound, Drug Substance, Drug Product or Licensed Product after having provided the other Party with an opportunity to review and approve (such approval not to be unreasonably withheld, conditioned or delayed) such statement; provided that failure to disapprove of such press release in writing within two (2) Business Days shall be deemed approval hereunder. Such Party shall give due consideration to any specific reasonable comments of the other Party on such text timely received from the other Party, subject to such Party's compliance with applicable Laws and stock exchange rules with respect to disclosure.

8.7 Filing, Registration or Notification of the Agreement. Protalix shall provide Chiesi with a proposed form of redacted copy of this Agreement (the "Redacted Agreement") for Chiesi's review and comment as soon as reasonably practicable after the Effective Date, and Protalix shall consider any comments from Chiesi in good faith; provided, however, that the final form of such Redacted Agreement shall be determined by Protalix. If a Party determines that it is required by Law to publicly file, register or notify this Agreement with a Governmental Authority, such Party shall (a) initially file the Redacted Agreement, (b) request, and use Commercially Reasonable Efforts to obtain, confidential treatment of all terms redacted from this Agreement, as reflected in the Redacted Agreement, for a period of at least [***] years, (c) permit the other Party to review and approve such request for confidential treatment and any subsequent correspondence with respect thereto at least [***] Business Days prior to its submission to such Governmental Authority, (d) promptly deliver to the other Party any written correspondence received by it or its representatives from such Governmental Authority with respect to such confidential treatment request and promptly advise the other Party of any other communications between it or its representatives with such Governmental Authority with respect to such confidential treatment request, (e) upon the written request of the other Party, request an appropriate extension of the term of the confidential treatment period, and (f) if such Governmental Authority requests any changes to the redactions set forth in the Redacted Agreement, use Commercially Reasonable Efforts to support the redactions in the Redacted Agreement as originally filed and shall not agree to any changes to the Redacted Agreement without first discussing such changes with the other Party and taking the other Party's comments into consideration when deciding whether to agree to such changes. Each Party shall be responsible for its own legal and other external costs in connection with any such filing, registration or notification.

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

Section 9. REPRESENTATIONS, WARRANTIES AND COVENANTS

9.1 Mutual Representations, Warranties and Covenants. Each of Chiesi and Protalix hereby represents and warrants to the other Party as of the Effective Date (and covenants as set forth in Sections 9.1(h), 9.1(i), 9.1(j), 9.1(k) and 9.1(l) below) as follows:

(a) It is duly organized, validly existing and in good standing under the Laws of the jurisdiction of its incorporation or formation, as applicable. It has the requisite corporate power and authority to conduct its business as presently being conducted and as proposed to be conducted by it.

(b) It has the requisite corporate power and authority to enter into this Agreement and to perform its obligations hereunder. All corporate actions on its part, necessary for (i) the authorization, execution, delivery and performance by it of this Agreement, and (ii) the consummation of the transactions contemplated hereby, have been duly taken.

(c) Assuming the due authorization, execution and delivery by the other Party, this Agreement constitutes a legally valid and binding obligation of such Party, enforceable against it in accordance with its terms (except in all cases as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, or similar Laws affecting the enforcement of creditors' rights generally and except that the availability of the equitable remedy of specific performance or injunctive relief is subject to the discretion of the court or other tribunal before which any proceeding may be brought).

(d) There is no contractual restriction or obligation binding on such Party which would be materially contravened by execution and delivery of this Agreement or by the performance of its terms. Apart from expiration or termination of any applicable waiting periods (including any extensions thereof) required by any applicable Law or governmental entity for antitrust purposes in the Territory, there are no governmental filings or consents necessary for the consummation of this Agreement and the transactions contemplated hereby.

(e) Such Party is not debarred, and such Party in relation to the Licensed Product is not using, has not used, and will not use in any capacity the services of any person debarred, in each case under Subsection 306(a), (b) of the Generic Drug Enforcement Act of 1992, or any non-U.S. equivalent Law to the foregoing.

(f) To such Party's knowledge, no representation or warranty made by it in this Agreement, nor any statement contained in any schedule hereto furnished by it, contains any untrue statement of a material fact or omits any material fact necessary to make the statements contained herein or therein not misleading.

(g) There is no litigation, proceeding or investigation pending or, to such Party's knowledge, threatened against such Party in any court or before any agency or regulatory body which would reasonably be expected to materially adversely affect such Party's ability or right to carry out the transactions contemplated by this Agreement.

(h) During the Term, each Party shall promptly notify the other Party in writing upon learning of any actual or threatened investigation, inquiry, action or proceeding before the FDA or any other Regulatory Authority in the Territory with respect to the Compound, Drug Substance, Drug Product or Licensed Product.

(i) Each Party shall (i) comply in all material respects with applicable anti-bribery Laws and the Chiesi Anti-Bribery Policy, attached hereto as Exhibit D, and (ii) adopt, implement and keep for the Term, reasonably adequate measures aimed at preventing the commission, even attempted, of conduct in violation in any material respect of anti-bribery Laws by its Affiliates, directors, representatives, employees, and/or consultants involved in the performance of this Agreement.

(j) Each Party and its Affiliates, directors, representatives, employees, and/or consultants involved in the performance of this Agreement, in performing their obligations under this Agreement shall not, directly or indirectly:

(i) offer, transfer, promise or pay money, commissions, compensation or any other benefit (including gifts, entertainment, or any other similar benefit, even low value or non-material benefits, unless they can be considered as low value courtesy benefits) in favor of public or private parties, in violation of applicable anti-bribery Laws, the Chiesi Anti-Bribery Policy and/or with the intention of or as a condition to obtaining illegal benefits in favor of Chiesi or Protalix;

(ii) direct a Third Party to carry out the activities set out in subsection (i) above;

(iii) give, transfer or promise money, commissions, compensation and rewards in kind (including gifts, entertainment or any other similar benefit, even low value or non-material benefits, unless they can be considered as low value courtesy benefits) to the other Party's directors, legal representatives, employees or whoever acts on behalf of such other Party, in violation of any applicable anti-bribery Law and beyond the limits set forth within the Chiesi Anti-Bribery Policy.

(k) Unless to the extent this provision would be a violation of any applicable Laws, Protalix shall promptly notify Chiesi at the following Chiesi e-mail address: groupcompliance@chiesi.com, and Chiesi shall promptly notify Protalix at the following Protalix e-mail address: moshe.manor@protalix.com, if such Party becomes aware of:

(i) any request, promise, offer, or donation of money, commission, compensation or rewards in kind (including gifts, entertainments, or any other similar benefit, even low value or non-material benefits) made to public officers, private parties or the other Party's directors, legal representatives or employees (or whoever acts on behalf of such other Party), in relation to the activities prohibited under Section 9.1(j);

(ii) any gift, entertainment or any other similar benefit, even non-material benefits, carried out by either Party in breach of the provisions of Section 9.1(j); or

(iii) any investigation, administrative suit, law suit or other procedure involving such Party in relation to corruption, bribery or any other similar harmful act to the public treasury.

(l) Each Party shall conduct, and shall use reasonable efforts to cause its Affiliates to conduct, all its activities contemplated under this Agreement in accordance with all applicable Laws of the Country in which such activities are conducted.

(m) Each Party hereby acknowledges and agrees that the Protalix Patent Rights and the Protalix Technology, to the extent licensed under this Agreement, constitute intellectual property as defined in Section 101 of the United States Bankruptcy Code subject to the provisions of Section 365(n) of the United States Bankruptcy Code; provided that no decision is made at this time with respect to any potential acceptance or rejection of this Agreement pursuant to the United States Bankruptcy Code at any time. The Parties further agree that Chiesi, as licensee of Protalix Patent Rights and Protalix Technology under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any Country having jurisdiction over Protalix or its assets subject to Chiesi's compliance in all material respects with all of its obligations thereunder. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Protalix under the U.S. Bankruptcy Code and any foreign equivalent thereto in any Country having jurisdiction over Protalix or its assets, Chiesi will be entitled, subject to applicable Laws, and at Chiesi's sole cost and expense, to a complete duplicate of (or full access to, as appropriate) any such Protalix Patent Rights and Protalix Technology and all embodiments of such intellectual property, and same, if not already in its possession, will be promptly delivered to Chiesi (or, as appropriate, Chiesi will be promptly provided access thereto) (i) upon any such commencement of a bankruptcy proceeding with respect to Protalix upon its written request therefor, unless Protalix elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i) above, following any such commencement of a bankruptcy proceeding with respect to Protalix and the rejection of this Agreement by or on behalf of Protalix upon written request therefor by Chiesi.

9.2 Additional Representations, Warranties and Covenants of Protalix. Protalix hereby further represents and warrants to Chiesi as of the Effective Date (and covenants as set forth in Sections 9.2(f), 9.2(g), 9.2(h), 9.2(i), 9.2(n), 9.2(r) and 9.2(s) below), that, except as set forth in any publically available filings of Protalix or its Affiliates, and solely in respect of the Territory:

(a) Exhibit A contains a complete and correct list as of the Effective Date of all Patents and Patent Applications owned by Protalix covering the Compound, any Licensed Product and the System.

(b) Protalix is the sole and exclusive owner of, or has exclusive rights to, all of the Protalix Patent Rights in existence on the Effective Date that relate to the Compound and/or the Licensed Product in the Field, and the Protalix Patent Rights set forth on Exhibit A are in full force and effect and free and clear of all liens and other encumbrances, security interests or options (other than pursuant to any agreements, secured debt or other financing referenced in Protalix's or its Affiliates' publically available filings).

(c) Protalix has the right to grant the licenses and rights in the Protalix Technology it purports to grant to Chiesi hereunder. For the avoidance of doubt, the foregoing representation and warranty shall not be deemed a representation or warranty with respect to non-infringement, which representation and warranty is solely addressed in Section 9.2(k).

(d) The Protalix Patent Rights and Protalix Technology include all of the Patent and other intellectual property rights owned or Controlled by Protalix or its Affiliates that are necessary for the Commercialization of the Licensed Product. The Protalix Patent Rights have been prosecuted and maintained in accordance with all applicable Laws in all material respects.

(e) No government funding, facilities or resources of a university, college, other educational institution, research center or Regulatory Authority was used in the creation or development of any Protalix Patent Rights and Protalix Technology, other than grants received from the Office of Chief Scientist of the Israeli Ministry of Industry, Trade and Labor.

(f) Any Third Party License relating to the rights licensed to Chiesi under Section 2.1 (and, as a consequence, may also relate to other provisions of this Agreement) is a legal and valid obligation binding upon Protalix and, to Protalix's knowledge, the relevant Third Party licensor (in each case, subject to the effect of any applicable bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditors' rights generally and subject, as to enforceability, to the effect of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law)), and authorizes, as necessary, Protalix to grant the sublicense(s) granted to Chiesi under this Agreement. As of the Effective Date, Protalix is in compliance in all material respects with any such Third Party License and Protalix covenants that during the Term it shall not modify or amend any Third Party License in a manner that would materially adversely affect Chiesi's access or rights hereunder without the prior written consent of Chiesi. Protalix has received no notices, whether written or oral, from any Third Party licensor alleging any past or present breach by Protalix of the terms of any such Third Party License. Protalix has issued no notices, whether written or oral, to any Third Party licensor alleging any past or present breach by any Third Party licensor of the terms of the relevant Third Party License. Protalix has provided Chiesi with true, correct and complete copy of any Third Party License, including any amendments thereto.

(g) Protalix shall not take any action that would materially adversely affect the rights granted to Chiesi hereunder with respect to any Third Party License, including selling, assigning or transferring the rights of Protalix under any Third Party License with respect to the Protalix Patent Rights and Protalix Technology, in each case, as relate to the Compound and/or the Licensed Product in the Field in the Territory, without Chiesi's prior written consent. Protalix shall: (i) comply in all material respects with and perform all of its material duties and obligations under any Third Party License relating to the Protalix Patent Rights and Protalix Technology, in each case, as relate to the Compound and/or the Licensed Product in the Field in the Territory; (ii) not intentionally take or fail to take any action within Protalix's reasonable control under any Third Party License that would materially adversely affect Chiesi's rights under this Agreement; (iii) use its Commercially Reasonable Efforts to enforce the provisions of any Third Party License against the relevant Third Party licensor; and (iv) not modify, amend or terminate any Third Party License with respect to the Protalix Patent Rights or Protalix Technology, in each case, as relate to the Compound and/or the Licensed Product in the Field in the Territory, in a manner that would materially adversely affect Chiesi's rights under this Agreement, without the prior written consent of Chiesi.

(h) Subject to Section 8, Protalix shall promptly notify Chiesi (other than to the extent Protalix, acting reasonably, determines that such notice could waive attorney-client privilege or any other legal privilege held by Protalix, or would otherwise breach a confidentiality provision or obligation) in writing of (i) any actual or threatened in writing default (including failure to pay royalties when due, if applicable), breach, suspension of compliance or performance, or termination (in whole or in part) under any Third Party License that relates to the Protalix Patent Rights or Protalix Technology, in each case, as relates to the Compound and/or the Licensed Product in the Field in the Territory, and which would materially adversely affect Chiesi's rights under this Agreement; and (ii) the actual or threatened in writing commencement of any dispute, claim, suit, litigation or arbitration proceeding related to the any Third Party License that relates to the Protalix Patent Rights or Protalix Technology, in each case, as relates to the Compound and/or the Licensed Product in the Field in the Territory, and which would materially adversely affect Chiesi's rights under this Agreement. Each such notification shall contain a summary of the event described therein. At the request of Chiesi, and subject to Section 8, Protalix shall (other than to the extent Protalix, acting reasonably, determines that to do so could waive attorney-client privilege or any other legal privilege held by Protalix, or would otherwise breach a confidentiality provision or obligation) (x) promptly provide to Chiesi full particulars, of which it is aware, in writing of the applicable matter; and (y) keep Chiesi reasonably informed as to the status and proposed resolution of each such matter.

(i) In the event that Protalix receives notice of any default (including failure to pay royalties or other amounts when due) or breach under any Third Party License that relates to the Protalix Patent Rights or Protalix Technology, in each case, as relates to the Compound and/or the Licensed Product in the Field in the Territory and which would materially adversely affect Chiesi's rights under this Agreement, and (i) has not cured such breach or default within ten (10) Business Days of receiving such notice, (ii) has not procured the entry by Chiesi into a Standby License as described in Section 2.2(d), and (iii) the amount of, and liability for, such breach or default is not disputed by Protalix (acting in good faith) or has been resolved in Chiesi's favor under Section 14.3, then Chiesi shall be entitled, but not obligated, to undertake payment or performance of the applicable underlying obligation on behalf of Protalix as necessary to cure such default or breach and to offset, against amounts payable to Protalix under this Agreement, any reasonable out-of-pocket costs and expenses incurred by Chiesi in the course thereof. In the event and to the extent that Protalix disputes the existence of such breach or default (acting in good faith), either Party may by written notice escalate the matter for discussions between the Chief Executive Officers of each Party to negotiate an agreed approach to the alleged breach or default and, to the extent the Parties cannot reach such agreement within thirty (30) days of the receipt of such notice, the Parties shall refer the matter for expert determination in accordance with Section 14.3.

(j) There is no material active, pending or, to Protalix's knowledge, threatened litigation or re-examination, pre- or post-grant or inter partes review, interference, derivation, opposition, claim of invalidity or other claim or proceeding (including in the form of any offer to obtain a license) alleging the invalidity, misuse, unregisterability, unenforceability or non-infringement of any Protalix Patent Rights, or challenging Protalix's ownership of, or Protalix's right to practice or license, any Protalix Patent Rights, or alleging any adverse right, title or interest with respect thereto (in each case, solely as relates to the Compound and/or the Licensed Product in the Field in the Territory).

(k) To the knowledge of Protalix after a reasonable internal inquiry of its executive officers and legal personnel, the practice of the Protalix Patent Rights and Protalix Technology in relation to the Compound and/or the Licensed Product in the Field in the Territory, and the Manufacture, use of the Compound, Drug Substance and/or Drug Product or Commercialization of Licensed Product (as now formulated) as contemplated under this Agreement, does not and will not infringe any issued Patent of any Third Party that exists on the Effective Date or, if and when issued, any Valid Claim within any Third Party Patent Application published before the Effective Date.

(l) Protalix and its Affiliates have complied in all material respects with all applicable Laws, with respect to the Development, Manufacture, use and handling of Compound, Drug Substance, Drug Product and Licensed Product.

(m) Protalix has not received any Form 483 observations, warning letters or other communications from a Regulatory Authority which would reasonably be expected to adversely impact the Development, Manufacture, use, handling of Compound, Drug Substance and/or Drug Product or the Commercialization of Licensed Product in any material respect.

(n) Drug Product (and Compound and Drug Substance) supplied by Protalix to Chiesi hereunder, prior to delivery by Protalix under Section 4.7: (i) will be Manufactured and stored in material compliance with the Product Specifications, GMP and all other provisions of this Agreement, the Quality Agreement and applicable Laws, including applicable environmental Laws, in force at the time of Manufacture, (ii) will not contain any material that would cause the Compound, Drug Substance and/or Drug Product to be adulterated or misbranded within the meaning of any applicable Laws and (iii) shall be free from defects in material and workmanship in all material respects.

(o) To Protalix's knowledge, there are no material investigations, inquiries, actions or other proceedings pending before FDA, EMA or any other Regulatory Authority with respect to the Compound, Drug Substance, Drug Product or Licensed Product.

(p) Protalix has not withheld any data or information known to Protalix related to the Compound, Drug Substance, Drug Product or Licensed Product, including, but not limited to, preclinical and clinical data, regulatory filings and regulatory communications, in each case, that would reasonably be expected to be material to Chiesi's decision to enter into this Agreement.

(q) The information contained in the excel file provided by Protalix to Chiesi via e-mail on July 18, 2018 relating to the costs sustained by Protalix through May, 2018 for the Development of the Compound, Drug Substance, Drug Product and Licensed Product is accurate in all material respects.

(r) During the Term, Protalix shall not grant any rights in violation of the rights and licenses granted herein, and Protalix shall not assign the Protalix Patent Rights and/or material Protalix Technology in the Territory except to a permitted assignee of this Agreement pursuant to Section 15.6.

(s) Protalix shall perform its obligations under this Agreement in compliance in all material respects with applicable provisions of the International Federal of Pharmaceutical Manufacturers & Associations Code of Practice and applicable provisions of the Chiesi Code of Ethics and Conduct, attached hereto as Exhibit E.

(t) Protalix has obtained the assignment from the inventors of all inventorship rights in the Protalix Patent Rights owned by Protalix.

(u) As of the Effective Date, each of Protalix and Protalix Parent has complied, and upon and after the Effective Date each of Protalix and Protalix Parent shall comply, in all material respects with its respective obligations under the Indenture and each of the Indenture Security Documents, and Protalix covenants that during the Term neither it nor Protalix Parent shall modify or amend any provisions of the Indenture or any of the Indenture Security Documents in a manner that would constitute a breach of the terms of this Agreement. Without limitation of the foregoing, Protalix and Protalix Parent covenant to direct the proceeds of the Effective Date Payment as set forth under Section 5.1 of both this Agreement and the Ex-US Agreement, and of all Event Milestone Payments as set forth under Section 5.2 of both this Agreement and the Ex-US Agreement, as required by the terms of the Indenture. Neither Protalix nor Protalix Parent has received any notices, whether written or oral, from the Indenture Trustee, the Israeli Security Trustee, or the Collateral Agent alleging any past or present breach by Protalix or Protalix Parent of the terms of the Indenture or any of the Indenture Security Documents. Protalix has provided Chiesi with true, correct and complete copies of the Indenture and the Indenture Security Documents, including any amendments to any documentation thereof.

(v) Other than to the extent Protalix, acting reasonably, determines that to do so could waive attorney-client privilege or any other legal privilege held by Protalix, or would otherwise breach a confidentiality provision or obligation of Protalix: (i) Protalix shall promptly notify Chiesi in writing of any event, act or condition which with notice or lapse of time, or both, would constitute an Event of Default (as defined in the Indenture) under the Indenture, and of any notice of any default or breach under the Indenture or the Indenture Security Documents; (ii) each such notification shall contain a summary of the event, act or condition described therein, (iii) at the reasonable request of Chiesi, Protalix shall (x) promptly provide to Chiesi full particulars, of which it is aware, of the applicable matter; and (y) keep Chiesi reasonably informed as to the status and proposed resolution of each such matter. In the event that Protalix and Protalix Parent have not cured any breach or default of Protalix's financial obligations under the Indenture or Indenture Security Documents with respect to payment of amounts required to be paid thereunder (excluding repayment of principal) within five (5) Business Days of receiving notice of such breach or default then Chiesi shall be entitled, but not obligated, to undertake payment or performance of such applicable underlying payment obligation on behalf of Protalix or Protalix Parent as necessary to cure such default or breach and to offset, against amounts payable to Protalix under this Agreement and the Ex-US Agreement, any such amounts paid by Chiesi.

(w) Upon and following the Effective Date, Protalix and Protalix Parent promptly shall (at Chiesi's sole cost and expense) (i) use Commercially Reasonable Efforts to obtain the release of that portion of Collateral (as defined in the Indenture) relevant under this Agreement and the Ex-US Agreement from the Note Liens (as defined in the Indenture) in accordance with the Note Documents (as defined in the Indenture), including, if reasonably necessary, by seeking the consent of the holders of a majority of the aggregate principal amount of the outstanding Notes (as defined in the Indenture) should that be required thereunder, and (ii) use Commercially Reasonable Efforts to cause the Indenture Trustee, the Collateral Agent and the Israeli Security Trustee to execute and deliver all documents, and to take all other actions, reasonably required to evidence such release. Notwithstanding the foregoing, prior to incurring any such cost or expense in Protalix's control (for example, not including legal costs incurred by the Indenture Trustee or Israeli Security Trustee for which Protalix may be responsible) for which Chiesi is responsible under this Section 9.2(w) in excess of [***], Protalix shall obtain Chiesi's approval to incur such costs; provided that if Chiesi does not grant such consent with respect to any costs or expenses reasonably required to be incurred for Protalix to comply with its obligations in this Section 9.2(w), Protalix shall not be obligated to take any actions under this Section 9.2(w), unless and until Chiesi consents to Protalix incurring such costs.

9.3 Additional Representation and Warranty of Chiesi. Chiesi hereby further represents and warrants to Protalix as of the Effective Date, that to the knowledge of Chiesi, neither Chiesi nor any of its Affiliates (a) is engaged in the Development or Commercialization of a Competing Product on the Effective Date nor (b) has in effect on the Effective Date a written plan to Develop a Competing Product.

9.4 Disclaimer of Warranty. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY, AND EACH PARTY DISCLAIMS ALL, REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE COMPOUND, DRUG SUBSTANCE, LICENSED PRODUCT, SUCH PARTY'S TECHNOLOGY OR PATENT RIGHTS, OR ANY OTHER MATTER, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

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

Section 10. NON-COMPETITION

[***]

Section 11. TERM

This Agreement shall be effective as of the Effective Date and shall remain in effect until the later of (i) the expiration of the last enforceable Protalix Patent Right, or (ii) the 15th anniversary of Launch in the Territory, unless earlier terminated pursuant to Section 12 (the "Term") [***].

Section 12. TERMINATION

12.1 Termination Rights. This Agreement may be terminated as follows:

(a) Mutual Agreement. This Agreement may be terminated in its entirety at any time upon mutual written agreement between the Parties.

(b) Material Breach. Either Party may terminate this Agreement at any time upon written notice to the other Party if the other Party is in material default or breach of this Agreement and such material default or breach is not cured within (i) thirty (30) days after written notice thereof is delivered to the defaulting or breaching Party, or (ii) in the case of a breach that cannot be cured within thirty (30) days, within a reasonable period not exceeding ninety (90) days after written notice thereof is delivered to the defaulting or breaching Party, so long as the breaching Party is making a good faith effort to cure such default. For the avoidance of doubt, a [***] does not constitute a material breach of this Agreement and shall not entitle Chiesi to terminate this Agreement. Termination shall not be the sole remedy for material breach of this Agreement, and a Party may choose to continue to perform hereunder and in response to any material breach may bring a claim for damages and other available remedies under this Agreement including, where applicable, a claim for injunctive relief, and bringing such a claim in good faith shall not constitute a breach of this agreement.

(c) Insolvency. Either Party may terminate this Agreement upon written notice to the other Party, if the other Party (i) files, or has filed against it, a petition for voluntary or involuntary bankruptcy or pursuant to any other insolvency Law, or (ii) applies for, or consents to, the appointment of a trustee, receiver or custodian for a substantial part of its property or business.

(d) Change of Control. Protalix may terminate this Agreement upon written notice, and agreement to pay the Buy-Back Payment, to Chiesi, upon the occurrence of a Change of Control in respect of Chiesi; provided, however, that such written notice must be provided within thirty (30) days of Protalix first becoming aware of the Change of Control. For purposes of this Section 12.1(d), "Buy-Back Payment" means [***]; provided, however that if prior to the occurrence of such Chiesi Change of Control one or more of Event Milestones 2 through 4 have been achieved, such [***] figure in Section 12.1(d)(ii) shall be increased by an amount equal to [***] of the amount of such achieved Event Milestone (for example, if Event Milestones 2 and 3 have been achieved prior to such Chiesi Change of Control, the figure in Section 12.1(d)(ii) shall be increased to [***]). Upon receipt of the termination notice from Protalix, Chiesi must within [***] issue an invoice for the applicable Buy-Back Payment. Such termination will take effect on the first Business Day following written agreement by Protalix to pay the applicable Buy-Back Payment, which must be delivered within [***] of receipt of an invoice provided by Chiesi for a Buy-Back Payment amount that is not disputed by Protalix in good faith. For the avoidance of doubt, until such dispute is resolved pursuant to Section 14.2, such termination will not take effect. For the avoidance of doubt, for so long as this Agreement and the Ex-US Agreement are both in effect, this Section 12.1(d) and Section 12.1(d) under the Ex-US Agreement shall both apply.

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

(e) Patent Challenge. Protalix may terminate this Agreement as provided in and in accordance with Section 2.7(b).

(f) [***]. Without limiting its rights under Section 12.1(b):

(i) Protalix may terminate this Agreement (i) in its entirety, upon at least [***] written notice to Chiesi if within [***] of receipt of Regulatory Approval of the Licensed Product in the Territory, Chiesi has not Launched for reasons within its reasonable control (and, for clarity, not for reasons outside Chiesi's reasonable control, i.e., a Force Majeure Event) the Licensed Product in Territory; provided that, if Chiesi delays Launch of the Licensed Product in excess of such [***] period pursuant to the exercise of its decision-making authority on the timing of the Launch based upon Chiesi's good faith evaluation of any risks associated with Competing Product Patents, pursuant to and in accordance with Section 3.5, then such [***] period shall be increased to (A) [***], if Event Milestone 2 has been achieved, or (B) [***], if Event Milestone 2 has not been achieved (in each case, solely for the period of such delay in accordance with Section 3.5), or (ii) upon at least [***] written notice to Chiesi, if for a period of [***] at any time following Launch of the Licensed Product in the Territory, [***].

(ii) Protalix may terminate this Agreement in its entirety, in the event that Chiesi or any of its Affiliates (including through any acquisition), directly or indirectly, alone or in collaboration with any Third Party, Develop or Commercialize in the Territory any Competing Product; provided that, and for the avoidance of any doubt, if Chiesi acquires a Competing Product through an acquisition of all or substantially all of the assets of a Third Party, whether by merger, sale of stock, all or substantially all of such Third Party's assets or other similar transaction, Chiesi or its successor entity, as applicable, shall have ninety (90) days from such acquisition to, at Chiesi's option, (x) permanently cease the Development and Commercialization of (and agree to not in the future to Develop or Commercialize) such Competing Product in the Territory, or (y) sell or otherwise dispossess ownership of the Competing Product in the Territory, prior to Protalix being able to exercise its termination rights under this Section 12.1(f)(ii). For so long as this Agreement remains in effect, this Section 12.1(f)(ii) hereby amends, replaces and supersedes in its entirety Section 12.1(f)(ii) of the Ex-US Agreement, which shall be of no further force or effect for so long as this Agreement remains in effect.

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

12.2 Continuing and Accrued Obligations. After notice of termination is given and, subject to the further provisions of this Section 12.2, prior to the effective date of termination, this Agreement, including all payment obligations hereunder, shall continue in full force and effect, and the Parties shall continue to carry out and perform their respective Development, Manufacturing and Commercialization activities in accordance with this Agreement through the effective date of termination. Without limitation of the foregoing, expiration or termination of this Agreement for any reason (i) shall be without prejudice to and shall not impair or limit in any manner (A) Protalix's right to receive payment from Chiesi of the Price (and any reconciliation amounts calculated in accordance with Section 4.6(h)) in respect of sales of Licensed Product in the Territory occurring prior to the effective date of such expiration or termination, whether or not the due date for such payment is after such effective date of expiration or termination, (B) Protalix's right to receive the applicable Event Milestone Payment in respect of any Event Milestone which occurs prior to the effective date of expiration or termination, whether or not the due date for such payment is after such effective date of expiration or termination, (C) Protalix's right to receive payment from Chiesi in accordance with this Agreement for any Licensed Product ordered by Chiesi pursuant to this Agreement prior to the effective date of such expiration or termination, whether or not the due date for such payment is after such effective date of expiration or termination, and (D) any remedies that either Party may have and (ii) 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 expiration or termination.

12.3 Effects of Termination. Upon expiration or the earlier effective date of termination of this Agreement in accordance with this Section 12 or Section 4.14(e), all licenses and rights provided for herein, and all obligations of the Parties hereunder, shall terminate and this Agreement shall cease to be of further force or effect except as otherwise provided for in Section 15.5.

(a) Upon expiration or termination of this Agreement for any reason:

(i) Chiesi shall, promptly after such expiration or termination, provide to Protalix or its designee the following materials; provided that such materials shall be provided in the form and format in which such materials are maintained by Chiesi in the ordinary course of business (provided that Chiesi shall use Commercially Reasonable Efforts to provide such materials in a form and format useable by Protalix), and Chiesi shall not be required to prepare any new data, reports or information solely for purposes of transfer to Protalix:

(A) all regulatory filings and Regulatory Approvals to the extent related to the Drug Substance, Drug Product or Licensed Product;

(B) all pre-clinical and clinical data, reports and information (including drug master files) in Chiesi's possession or control to the extent relating to a Licensed Product, Drug Product or Drug Substance (including any Jointly Owned Clinical Data);

(C) all reports, records, regulatory correspondence and other materials in Chiesi's possession or control to the extent relating to the pre-clinical and clinical development of the Drug Substance, Drug Product or Licensed Product, and also including, if applicable, any information contained in the global safety database established and maintained by Chiesi for the Licensed Product; and

(D) all Product Marks actually used in commerce by Chiesi or its Affiliates for the Licensed Product, excluding the corporate or trade name or logo of Chiesi or its Affiliates.

(ii) Effective upon such expiration or termination:

(A) Chiesi hereby does (and shall) assign to Protalix, or a Protalix Affiliate identified by Protalix, (i) all of Chiesi's right, title and interest in and to the materials transferred or delivered or deliverable by Chiesi pursuant to Section 12.3(a)(i), including the goodwill attendant to any Product Marks, to the extent Chiesi Controls such materials, and (ii) in respect of any Jointly Owned Clinical Data, its undivided one-half interest in such Jointly Owned Clinical Data; with respect to the Product Marks, Chiesi shall execute an assignment of such Product Marks in favor of Protalix and Protalix shall be responsible for recording such assignment with the appropriate governmental trademark authorities. Chiesi shall cooperate in facilitating such assignment and recordation by timely executing all necessary documents provided to it by Protalix;

(B) Chiesi hereby does (and shall) assign to Protalix any applicable sublicenses to the extent related to the Licensed Product and/or Third Party agreements, with respect to significant services to be performed by Third Parties to the extent related to the Licensed Product in the Field, unless Protalix has advised Chiesi that it will not require such assignment.

(iii) Without limitation of the generality of the foregoing, the Parties shall use diligent efforts to complete the transition of the Commercialization of the Licensed Product in the Field in the Territory hereunder to Protalix (or its sublicensee or Third Party designee) as soon as is reasonably possible.

(b) Following any expiration or termination of this Agreement, each of Chiesi and Protalix shall, upon request of the other Party, return or destroy all Protalix Confidential Information and Chiesi Confidential Information, respectively, disclosed to it pursuant to this Agreement, including all copies and extracts of documents, as promptly as practicable following receipt of such request, except (i) that one (1) copy may be kept for the purpose of complying with continuing obligations under this Agreement and (ii) to the extent and for so long as necessary to perform its obligations or exercise its rights under this Section 12.2.

(c) Following termination of this Agreement, other than termination by Protalix pursuant to Sections 12.1(b), 12.1(c), 12.1(d), 12.1(e), or 12.1(f), notwithstanding the termination of the licenses and rights granted by Protalix to Chiesi hereunder, Chiesi and its Affiliates shall have the right to continue to sell their existing inventories of the Licensed Product for a period not to exceed [***] after the effective date of such termination and Protalix shall continue to receive any amounts due hereunder in respect of such Net Sales, including any applicable Event Milestone Payments, or reconciliation amounts calculated in accordance with Section 4.6(h). Following termination of this Agreement (or, in the event of termination by Protalix pursuant to Sections 12.1(b), 12.1(c), 12.1(d), 12.1(e) or 12.1(f), following such [***] period), Chiesi and its Affiliates shall promptly return to Protalix or destroy (at Protalix's sole discretion) all inventory of Licensed Products in its possession as of the effective date of termination (or as of the end of such [***] period, as applicable).

Section 13. INDEMNIFICATION AND INSURANCE

13.1 Indemnification by Chiesi. Subject to Sections 13.3 and 13.4, Chiesi shall indemnify, defend and hold Protalix, its Affiliates, and their respective directors, officers, employees, consultants, contractors, sublicensees and agents (collectively, the "Protalix Indemnitees") harmless from and against any and all claims, suits, proceedings or causes of action ("Claims") brought by a Third Party against such Protalix Indemnitee, including any damages or other amounts payable to such Third Party and reasonable attorneys' fees and costs of litigation (collectively, "Damages"), in each case to the extent resulting from or based on: (a) any Extension Studies conducted by Chiesi for the Licensed Product and the Registry; (b) the Commercialization of the Licensed Product or the performance of [***] activities after [***] or Commercial Medical Affairs and Pharmacovigilance activities by Chiesi or any of its Affiliates; (c) any taxes for which Chiesi is responsible under Sections 4.6(b) and 6.7; (d) Chiesi's breach of this Agreement or of any of its representations, warranties or covenants herein; or (e) the negligence or willful misconduct of, or violation of applicable Laws by, Chiesi or its Affiliates, or their respective employees, contractors or agents in the performance of this Agreement; in each case, to the extent not resulting from or related to Protalix's breach of its obligations under this Agreement or its negligence or willful misconduct.

13.2 Indemnification by Protalix. Subject to Sections 13.3 and 13.4, Protalix shall indemnify, defend and hold Chiesi, its Affiliates, and their respective directors, officers, employees, consultants, contractors and agents (collectively, the "Chiesi Indemnitees") harmless from and against any and all Claims brought by a Third Party against such Chiesi Indemnitee, including any Damages, in each case to the extent resulting from or based on: (a) any Development work conducted by Protalix for the Licensed Product (including, for clarity, the Extension Studies conducted by Protalix pursuant to Section 3.2(e)); (b) Protalix's breach of this Agreement or of any of its representations, warranties or covenants herein; (c) any claim of infringement of an issued Patent or Technology to the extent such claim arises from a breach or alleged breach of Section 9.2(k); or (d) the negligence or willful misconduct of, or violation of applicable Laws by, Protalix, its Affiliates or sublicensees, or their respective employees, contractors or agents in the performance of this Agreement; in each case, to the extent not resulting from or related to Chiesi's breach of its obligations under this Agreement or its negligence or willful misconduct.

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

13.3 Indemnification of Product Liability Claims. Notwithstanding any other provision of this Agreement, this Section 13.3 shall govern the allocation of liability with respect to any Third Party product liability Claim, including Claims of property injury, bodily injury or deaths related to the Licensed Product in the Territory (a "Third Party Product Claim").

(a) Subject to Section 13.4, Protalix shall indemnify and hold harmless the Chiesi Indemnitees from and against any and all Damages which a Chiesi Indemnitee may incur or suffer arising out of any Third Party Product Claim to the extent caused by or arisen from any defect in the Manufacturing of the Licensed Product by Protalix.

(b) Subject to Section 13.4 and except to the extent provided in subsection (a) above, Chiesi shall defend, indemnify and hold harmless the Protalix Indemnitees from and against any and all Damages arising out of any Third Party Product Claims to the extent caused by or arising out of any sale, use, importation, storage, handling, distribution, offer for sale (or other Commercialization) or sale of Licensed Product in the Territory.

13.4 Defense Procedures; Procedures for Third Party Claims.

(a) 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, employees, consultants, contractors, sublicensees and agents. In the event a Third Party Claim is asserted with respect to any matter for which a Party or any of its Affiliates, or any of their respective directors, officers, employees, consultants, contractors, sublicensees and agents (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 hereunder (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.

(b) Except as set forth in Section 7.8, 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, upon written notice to the Indemnifying Party, in which case, the Indemnifying Party shall be relieved of liability under Section 13.1, as applicable, solely for such Third Party Claim and related Damages.

(c) Without limiting the settlement rights set forth in Sections 7.7 and 7.8, neither Party will enter into any settlement of any suit involving Licensed Products that materially affects the other Party's rights or obligations with respect to the Licensed Product without the other Party's prior written consent (which consent shall not be unreasonably withheld, delayed or conditioned). The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, delayed or conditioned), effect any settlement of any pending or threatened litigation in which the Indemnified Party has sought indemnification hereunder by the Indemnifying Party, 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.

13.5 Insurance. The Parties shall maintain insurance with creditworthy insurance companies in full force and effect during the Term and, with respect to "claims made" policies, for a period of [***] after expiration or termination of this Agreement as follows: worker's compensation (if applicable), general liability, employers liability, clinical trial liability and product liability insurance coverage in such amounts and with such scope of coverages as are adequate to cover such Party's obligations under this Agreement and as are customary in the industry for companies of like size and activities. Upon written request, each Party shall provide evidence of such insurance to the other Party and ensure that the other Party will receive no less than thirty (30) days' notice of any cancellation or material change in such coverage.

13.6 Disclaimer of Liability for Consequential Damages. 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 CHIESI, PROTALIX OR ANY OF THEIR RESPECTIVE AFFILIATES. THE FOREGOING SENTENCE SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER Section 13 OR LIABILITIES RESULTING FROM A BREACH OF THE CONFIDENTIALITY OBLIGATIONS UNDER Section 8 ABOVE, OR ANY LIABILITY ARISING OUT OF THE INFRINGEMENT OF THE PROTALIX PATENT RIGHTS OR PROTALIX TECHNOLOGY INCLUDING, FOR CLARITY, ANY USE BY CHIESI OR ITS AFFILIATES OF THE PROTALIX PATENT RIGHTS OR PROTALIX TECHNOLOGY OTHER THAN AS EXPRESSLY PROVIDED FOR IN Section 2 AND PROVIDED THAT THIS SECTION 13.6 SHALL NOT RELIEVE EITHER PARTY FROM ITS PAYMENT OBLIGATIONS UNDER THIS AGREEMENT.

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

13.7 Sole Remedy. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT AND EXCEPT FOR ANY EQUITABLE REMEDIES THAT MAY BE AVAILABLE TO A PARTY, INDEMNIFICATION PURSUANT TO Section 13 SHALL BE THE SOLE AND EXCLUSIVE REMEDY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY) AVAILABLE TO PROTALIX OR CHIESI FOR THE MATTERS COVERED THEREIN.

13.8 Concurrency of Agreement and Ex-US Agreement. Notwithstanding anything to the contrary herein or in the Ex-US Agreement, each Party acknowledges and agrees (a) a Party shall not be entitled to duplicate recovery under a claim for indemnification or for other damages or losses under both this Agreement and the Ex-US Agreement with respect to the same indemnified Claim or the same damages or loss, respectively, and (b) any action taking under this Agreement or the Ex-US Agreement may also satisfy an obligation of such Party under the other such agreement (i.e., shall action will not be required to be taken twice if its single performance is able to satisfy obligations under both this Agreement and the Ex-US Agreement).

Section 14. GOVERNING LAW AND JURISDICTION

14.1 Governing Law. This Agreement shall be governed by and construed in accordance with the substantive Laws of the State of New York, without regard to conflicts of law rules. The provisions of the U.N. Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

14.2 Jurisdiction and Dispute Resolution Process. With the exception of those matters referred for resolution by independent accountants under Section 6.1(b), Section 6.6 or Section 6.7(c) or by independent consultants under Section 4.8(c) or by Joint Legal Counsel under Section 14.3, any dispute, controversy or claim arising out of or relating to this Agreement, or the interpretation or breach thereof, including disputes regarding the existence, validity or termination of this Agreement or the scope of the agreement to arbitrate herein (each, a "Dispute"), shall be determined in accordance with the provisions of this Section 14.2:

(a) If any Dispute arises, either Party may provide written notice of the Dispute to the other Party and request negotiation between the executive officers of each Party ("Dispute Notice"). Within fifteen (15) days after the delivery of a Dispute Notice, the executive officers shall confer in person or by teleconference to attempt to settle the Dispute. All communication between such executive officers shall not be construed as an admission or agreement as to the liability of any Party, nor be admitted in evidence in any related arbitration, litigation, or other adversary proceeding.

(b) If, within thirty (30) days after the delivery of a Dispute Notice, the Parties are unable to resolve the Dispute in writing, upon written notice by any Party to the other Party, such Dispute shall be determined exclusively by arbitration in London, England, before a panel of three (3) arbitrators in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC Rules"), except as modified herein;

(c) In any arbitration commenced pursuant to this Section 14.2:

(i) There shall be three arbitrators, one of which shall be nominated by Protalix and another of which shall be nominated by Chiesi, as provided in the ICC Rules. The third arbitrator, who shall serve as the president of the tribunal, shall be jointly nominated by the two Party-nominated arbitrators within twenty (20) days of the date of confirmation of the second arbitrator by the ICC. Any arbitrator not timely nominated as provided herein shall be appointed by the ICC Court.

(ii) The seat of arbitration shall be London, England. The language of the arbitration shall be English. The Parties agree that the award rendered by the arbitral tribunal shall be final and binding and enforceable against the Parties and their respective assets in any court of competent jurisdiction. Unless determined otherwise by the arbitral tribunal, [***]. The arbitral tribunal shall not award any damages excluded by Section 13.6.

(iii) Any arbitration hereunder shall be confidential, and neither the Parties nor their agents shall disclose to any Third Party the existence or status of the arbitration, any information made known or documents produced in the arbitration not otherwise available to them or in the public domain, or any awards arising from the arbitration, except and to the extent that disclosure is required by applicable Law or is required to protect or pursue a legal right.

(iv) For any proceeding in aid of arbitration or for preliminary relief to preserve the status quo or avoid irreparable harm prior to the appointment of an arbitral tribunal, each Party irrevocably and unconditionally consents and submits to the exclusive jurisdiction and venue of the courts located in England, and waives, to the fullest extent possible, any objection to the laying of venue in such courts. The arbitral tribunal also shall have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any provisional, temporary or preliminary relief issued by a court hereunder.

(v) In any action pursuant to Section 14.2 and in any action with respect to any arbitration award obtained pursuant to this Agreement or to the enforcement of such an award, the Parties agree to accept service of process in the manner provided for notices in this Agreement, and to waive any other requirements for service of process in any jurisdiction to the fullest extent permitted by Law.

(vi) Each Party shall continue to perform obligations hereunder, when any bona fide Dispute is pending.

14.3 Expert Legal Determination.

(a) In the event that the Parties are unable to agree on an approach to an alleged breach or default by Protalix of a Third Party License (in accordance with Section 9.2(i)), the Parties shall jointly engage an agreed-upon, independent law firm of reputable stature with relevant licensing expertise (specifically in respect of life science agreements) in the relevant jurisdiction ("Joint Legal Counsel") to provide its legal opinion as to existence of, and liability in respect of, such alleged breach or default of such Third Party License ("Joint Legal Opinion").

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

(b) [***]. Communications with Joint Legal Counsel, its work product, and the Joint Legal Opinion shall be privileged and confidential and shall not be disclosed to anyone other than the Parties, who will be Joint Legal Counsel's joint clients, except that a Party may disclose the Joint Legal Opinion in confidence to a court or arbitration tribunal if necessary to enforce its rights under this Agreement.

(c) If the Joint Legal Counsel takes the position in the Joint Legal Opinion that the alleged breach or default exists and is able to quantify the amount of liability relating to such breach or default, Chiesi shall be entitled to (but not obligated to) exercise the right set out in Section 9.2(i) to undertake payment or performance of the underlying obligation on behalf of Protalix as necessary to cure such default or breach and to offset, against amounts payable to Protalix under this Agreement, any reasonable out-of-pocket costs and expenses incurred by Chiesi in the course thereof.

(d) If the Joint Legal Counsel takes the position in the Joint Legal Opinion that the alleged breach or default does not exist (or if the Joint Legal Counsel is unable to reach a conclusion in the Joint Legal Opinion as to the existence or otherwise of the alleged breach or default), then Chiesi may not exercise the right set out in Section 9.2(i), and such alleged breach or default may not be again referred for determination under this Section 14.3.

Section 15. MISCELLANEOUS

15.1 Force Majeure. Neither Party hereto 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 Effective Date), 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.

15.2 Severability. If and solely to the extent that any provision of this Agreement shall be invalid or unenforceable, or shall render this entire Agreement to be unenforceable or invalid, 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.

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

15.3 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.

15.4 Entire Agreements; Amendments. This Agreement, together with the Quality Agreement(s), 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 Protalix and Chiesi before the date hereof with respect to the subject matter hereof, including the Confidential Disclosure Agreement between the Parties, dated May 24, 2017; provided, however, that, for the avoidance of doubt, the parties acknowledge and agree on behalf of themselves and their respective Affiliates that the Ex-US Agreement shall remain in full force and effect other than as expressly amended, superseded or supplemented hereby, and in consideration of the agreements and promises made by Chiesi herein, all provisions herein related to the Indenture, the Indenture Security Documents, the Indenture Collateral Agent, the Indenture Trustee, and the Israeli Security Trustee shall apply with equal force and effect with respect to the Ex-US Agreement, and shall remain in full force and effect and continue to apply under the Ex-US Agreement regardless of the termination of this Agreement at any time. All Confidential Information disclosed by either Party to the other Party prior to the Effective Date will be deemed to have been disclosed pursuant to this Agreement. None of the terms of this Agreement shall be amended, supplemented or modified except in writing signed by the Parties.

15.5 Survival. The provisions of Section 2.3 (Non-Assertion of Rights), Section 6.6 (Inspection of Records), Sections 8.1-8.6 and 8.7 (Confidentiality), Section 9.4 (Disclaimer of Warranty), Sections 12.2 and 12.3 (Continuing and Accrued Obligations; Effects of Termination), Sections 13.1-13.4, 13.6, 13.7 and 13.8 (Indemnification; Disclaimer of Liability for Consequential Damages; Sole Remedy; Concurrency of Agreement with Ex-US Agreement), Section 14 (Governing Law and Jurisdiction), and Section 15 (Miscellaneous), as well as (x) any other Sections or defined terms referred to in such Sections or necessary to give them effect and (y) 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.

15.6 Assignment; Binding Effect.

(a) Neither this Agreement nor any rights or obligations of either Party to this Agreement may be assigned or otherwise transferred by either Party without the consent of the other Party; provided, however, either Party may, without such consent, assign this Agreement, in whole or in part: (i) to any of its respective Affiliates; provided that such assigning Party shall remain jointly and severally liable with such Affiliate in respect of all obligations so assigned, or (ii) to a Third Party successor to all or substantially all of the assets of such Party whether by merger, sale of stock, all or substantially all of a Party's assets or other similar transaction, so long as such Third Party agrees in writing to be bound by the terms of this Agreement. Notwithstanding anything to the contrary herein, nothing herein shall prevent Protalix or Protalix Parent from engaging in any merger, consolidation, reorganization, sale or purchase of stock, or sale or purchase of assets, or undergoing any Change of Control.

(b) Any purported assignment in violation of this Section 15.6 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

15.7 Independent Contractor. The relationship between Protalix and Chiesi is that of independent contractors. Protalix and Chiesi are not joint venturers, partners, principal and agent, employer and employee, and have no other relationship other than independent contracting parties.

15.8 Notices. Each communication and document made or delivered by one Party to another under this Agreement shall be made in the English language. 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:

Moshe Manor
P.O. Box 455,
Carmiel 20100, Israel

with a copy to:

Yossi Maimon

If to Chiesi:

Chief Executive Officer
Largo F. Belloli 11/A,
43122 Parma, Italy

with a copy to:

General Counsel; and
Head of Global Corporate Development

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 second (2nd) 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 Section 15.8.

15.9 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either 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 either Party.

15.10 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective heirs, successors and permitted assigns.

15.11 Performance by Affiliates. To the extent that this Agreement imposes obligations on Affiliates of a Party, such Party agrees to cause its Affiliates to perform such obligations. Chiesi may use one or more of its Affiliates to exercise its rights or perform its obligations and duties hereunder, provided that Chiesi shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder, including, for the avoidance of doubt, in respect of any Net Sales of Licensed Products attributable to the Commercialization activities of any of Chiesi's Affiliates.

15.12 Counterparts. This Agreement 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. Signatures provided by facsimile transmission or in Adobe™ Portable Document Format (PDF) sent by electronic mail shall be deemed to be original signatures.

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

15.14 Equitable Remedies. The Parties agree that irreparable damage may occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that, without limitation of other remedies which may be available to a Party for breach of this Agreement by the other Party, the Parties shall be entitled to seek an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF the Parties hereto have caused this Agreement to be executed by their duly authorized officers as of the date first written above.

CHIESI FARMACEUTICI S.p.A.

By: /s/ Alberto Chiesi
Name: Alberto Chiesi
Title: President

CHIESI FARMACEUTICI S.p.A.

By: /s/ Ugo Di Francesco
Name: Ugo Di Francesco
Title: Chief Executive Officer

PROTALIX LTD.

By: /s/ Moshe Manor
Name: Moshe Manor
Title: President and Chief Executive Officer

Schedule 3.1 – Development Plan

[***]

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

Schedule 3.7 – Initial Draft Commercialization Plan

[***]

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

Schedule 5.3(i) – Example of Development Cost Detail

[***]

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

Schedule 7.1(b) – Specified Patent Applications

[***]

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

Exhibit A – Protalix Patent Rights

[***]

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

Exhibit B – Third Party Licenses

[***]

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

Exhibit C – Press Release

Protalix BioTherapeutics Expands Partnership with Chiesi Farmaceutici to Include Exclusive U.S. Rights for the Development and Commercialization of PRX-102 (pegunigalsidase alfa) for the Treatment of Fabry Disease

Protalix to receive $25 million upfront, an additional up to $20 million in development costs and an additional up to $760 million in potential regulatory and commercial milestone payments for the U.S. rights

U.S. partnership includes tiered royalties ranging from 15% to 40% on net sales

CARMIEL, Israel, July 24, 2018 — GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE American:PLX, TASE:PLX), a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®, today announced the expansion of its partnership with Chiesi Farmaceutici S.p.A., or Chiesi. Protalix and Chiesi entered into an exclusive U.S. license and supply agreement which grants to Chiesi the United States rights for the development and commercialization of PRX-102 (pegunigalsidase alfa), the Company's chemically modified version of the recombinant protein alpha-Galactosidase-A protein, for the treatment of Fabry disease. In October 2017, Protalix announced an exclusive partnership with Chiesi for the development and commercialization of PRX-102 for the treatment of Fabry disease outside the United States.

Under the terms of the U.S. license and supply agreement, Protalix is entitled to an upfront payment of $25 million from Chiesi and additional payments of up to a maximum of $20 million in development costs, capped at $7.5 million per year. Protalix is also eligible to receive an additional up to a maximum of $760 million, in the aggregate, in regulatory and commercial milestone payments, and tiered royalties ranging from 15% to 40% on net sales as consideration for product supply. Protalix will continue to be the manufacturer of PRX-102 for clinical development and commercial purposes.

"We are very pleased to expand our collaboration with Chiesi, a growing global company with well-established global commercial infrastructure with a fast growing commercial presence in the U.S. Chiesi's global investment of $95 million in upfront payments and development costs reimbursement, and additional up to a maximum of $1 billion in potential milestone payments, combined in the two agreements reflects Chiesi's true commitment to the Fabry space," commented Moshe Manor, Protalix's President and Chief Executive Officer. "Taking into consideration a $25 million upfront payment and shared development expenses, we expect our cash runaway to take us through the read outs of all of the Fabry clinical trials."

In pre-clinical trials, PRX-102 demonstrated a significantly enhanced circulatory half-life and higher enzyme activity in the target organs affected by Fabry disease when compared to currently available versions of the molecule. In clinical development, PRX-102 demonstrated strong positive safety and efficacy data in a phase I/II clinical trial. Fabry patients are currently being enrolled in a global, pivotal phase III clinical trial, and Protalix anticipates starting to report data from these studies in the first half of 2019.

“We believe PRX-102 has the potential to transform the treatment of Fabry disease and are excited to now have exclusive commercial rights to PRX-102 worldwide,” said Ugo Di Francesco, Chiesi’s Chief Executive Officer. “The more we work with Protalix and see the progress made in the development and the product’s characteristics, it becomes abundantly clear the significant role PRX 102 could have in the underserved Fabry market and to potentially change the treatment paradigm to the benefit of all stake holders. We believe this U.S. license agreement will bring many synergies in our fast growing U.S. presence in rare diseases.”

Additional details regarding the collaboration can be found in Protalix's Form 8-K to be filed with the Securities and Exchange Commission.

About Protalix BioTherapeutics, Inc.

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®. Protalix’s unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix’s first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (FDA) in May 2012 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights. Protalix’s development pipeline includes the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa for the treatment of Cystic Fibrosis; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

About Chiesi Farmaceutici S.p.A.

Based in Parma, Italy, Chiesi Farmaceutici is an international research-focused Healthcare Group, with over 80 years of experience in the pharmaceutical industry. Chiesi researches, develops and markets innovative drugs in the respiratory therapeutics, specialist medicine and rare disease areas. Its R&D organization is headquartered in Parma (Italy), and integrated with 6 other key R&D groups in France, the USA, the UK, Sweden and Denmark to advance Chiesi's pre-clinical, clinical and registration programmes. Chiesi employs nearly 5,300 people. For more information, visit www.chiesi.com.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms “expect,” “anticipate, “believe,” “estimate,” “project,” “plan,” “should” and “intend” and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause material differences include, among others: failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of our product candidates will not support our claims of superiority, safety or efficacy, that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks related to our ability to maintain and manage our relationship with Chiesi Farmaceutici and any other collaborator, distributor or partner; risks related to the ultimate purchase by Fundação Oswaldo Cruz of alfataliglicerase pursuant to the stated purchase intentions of the Brazilian Ministry of Health of the stated amounts, if at all; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase generally; risks related to our commercialization efforts for alfataliglicerase in Brazil; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the amount of our future revenues, operations and expenditures; risks related to the amount and sufficiency of our cash and cash equivalents; the risk that despite the FDA’s grant of fast track designation for pegunigalsidase alfa for the treatment of Fabry disease, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA’s ability to withdraw the fast track designation at any time; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in our preparation and filing of applications for regulatory approval; delays in the approval or potential rejection of any applications we file with the FDA or other health regulatory authorities, and other risks relating to the review process; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; and other factors described in our filings with the U.S. Securities and Exchange Commission. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Investor Contact

Marcy Nanus
Solebury Trout
646-378-2927
mnanus@soleburytrout.com

Source: Protalix BioTherapeutics, Inc.

Exhibit D – Chiesi Anti-Bribery Policy

[***]

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

Exhibit E – Chiesi Code of Ethics and Conduct

[***]

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

EXHIBIT 31.1

CERTIFICATION

I, Moshe Manor, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2018

/s/ Moshe Manor
Moshe Manor
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Yossi Maimon, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 7, 2018

/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 September 30, 2018 as filed with the Securities and Exchange Commission (the "Report"), I, Moshe Manor, President and Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

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

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

Date: November 7, 2018

/s/ Moshe Manor
Moshe Manor
President and Chief Executive Officer

EXHIBIT 32.2

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2018 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: November 7, 2018

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