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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2025

OR

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

For the transition period from _____ to_____

001-33357
(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**65-0643773**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2 University Plaza, Suite 100, Hackensack, NJ	**07601**
(Address of principal executive offices)	**(Zip Code)**

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

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

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

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

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

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

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

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

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

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

On November 1, 2025, approximately 80,421,181 shares of the Registrant's common stock, $0.001 par value, were outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,647	$ 19,760
Short-term bank deposits	15,723	15,070
Accounts receivable	14,425	2,909
Other assets	1,452	1,096
Inventories	21,255	21,243
Total current assets	$ 66,502	$ 60,078
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 549	$ 462
Property and equipment, net	4,724	4,591
Deferred income tax asset	2,679	2,856
Operating lease right of use assets	7,810	5,430
Total assets	$ 82,264	$ 73,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,375	$ 4,533
Other	15,173	19,588
Operating lease liabilities	1,397	1,500
Total current liabilities	$ 21,945	$ 25,621
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 631	$ 559
Operating lease liabilities	6,780	4,026
Total long term liabilities	$ 7,411	$ 4,585
Total liabilities	$ 29,356	$ 30,206
COMMITMENTS		
STOCKHOLDERS' EQUITY	52,908	43,211
Total liabilities and stockholders' equity	$ 82,264	$ 73,417

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

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

	Nine Months Ended		Three Months Ended	
	September 30, 2025	September 30, 2024	September 30, 2025	September 30, 2024
REVENUES FROM SELLING GOODS	$ 43,108	$ 34,820	$ 17,673	$ 17,839
REVENUES FROM LICENSE AND R&D SERVICES	514	361	178	120
TOTAL REVENUE	43,622	35,181	17,851	17,959
COST OF GOODS SOLD	(22,374)	(20,433)	(8,324)	(8,375)
RESEARCH AND DEVELOPMENT EXPENSES	(13,934)	(8,846)	(4,467)	(2,998)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(8,156)	(9,194)	(2,929)	(2,595)
OPERATING INCOME (LOSS)	(842)	(3,292)	2,131	3,991
FINANCIAL EXPENSES	(808)	(1,056)	(180)	(299)
FINANCIAL INCOME	818	1,186	288	151
FINANCIAL INCOME (EXPENSES), NET	10	130	108	(148)
INCOME (LOSS) BEFORE TAXES ON INCOME	(832)	(3,162)	2,239	3,843
TAXES ON INCOME (TAX BENEFIT)	268	400	(116)	607
NET INCOME (LOSS)	$ (1,100)	$ (3,562)	$ 2,355	$ 3,236
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ (0.01)	$ (0.05)	$ 0.03	$ 0.04
DILUTED	$ (0.01)	$ (0.05)	$ 0.03	$ 0.03
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	78,225,112	73,301,091	79,281,685	73,549,745
DILUTED	78,225,112	73,301,091	80,814,564	81,217,068

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

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

	Common Stock (1)	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
Balance at January 1, 2024	**72,952,124**	**$ 73**	**$ 415,045**	**$ (381,549)**	**$ 33,569**
Changes during the nine-month period ended September 30, 2024:					
Initial adoption of ASU 2020-06			(393)	224	(169)
Share-based compensation related to stock options			1,191		1,191
Share-based compensation related to restricted stock awards	681,459	1	1,407		1,408
Net loss for the period				(3,562)	(3,562)
Balance at September 30, 2024	**73,633,583**	**$ 74**	**$ 417,250**	**$ (384,887)**	**$ 32,437**
Balance at January 1, 2025	**75,850,275**	**$ 76**	**$ 421,528**	**$ (378,393)**	**$ 43,211**
Changes during the nine-month period ended September 30, 2025:					
Issuance of common stock under the Sales Agreement, net	2,775,215	3	6,809		6,812
Share-based compensation related to stock options			1,004		1,004
Share-based compensation related to restricted stock awards	559,210	*	561		561
Exercise of warrants and options	1,156,625	1	2,419		2,420
Net loss for the period				(1,100)	(1,100)
Balance at September 30, 2025	**80,341,325**	**$ 80**	**$ 432,321**	**$ (379,493)**	**$ 52,908**
Balance at June 30, 2024	**73,292,674**	**$ 73**	**$ 416,631**	**$ (388,123)**	**$ 28,581**
Changes during the three-month period ended September 30, 2024:					
Share-based compensation related to stock options			358		358
Share-based compensation related to restricted stock awards	340,909	1	261		262
Net income for the period				3,236	3,236
Balance at September 30, 2024	**73,633,583**	**$ 74**	**$ 417,250**	**$ (384,887)**	**$ 32,437**
Balance at June 30, 2025	**79,732,115**	**$ 80**	**$ 431,671**	**$ (381,848)**	**$ 49,903**
Changes during the three-month period ended September 30, 2025:					
Share-based compensation related to stock options			405		405
Share-based compensation related to restricted stock awards	559,210		193		193
Exercise of options	50,000	*	52		52
Net income for the period				2,355	2,355
Balance at September 30, 2025	**80,341,325**	**$ 80**	**$ 432,321**	**$ (379,493)**	**$ 52,908**

*Represents an amount equal to less than $1.

(1) Common stock, $0.001 par value; Authorized – as of September 30, 2025 and December 31, 2024 – 185,000,000 shares.

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

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

	Nine Months Ended	
	September 30, 2025	September 30, 2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,100)	$ (3,562)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation	1,565	2,599
Depreciation	1,078	970
Financial expenses, net	136	173
Changes in accrued liability for employee rights upon retirement	14	32
Changes in deferred income tax asset	177	236
Gain on amounts funded in respect of employee rights upon retirement	(18)	(20)
Gain on sale of fixed assets		(3)
Changes in operating assets and liabilities:		
Decrease (Increase) in accounts receivable-trade and other assets	(11,768)	3,069
Changes in operating lease right of use assets, net	(62)	13
Decrease (increase) in inventories	(12)	1,846
Decrease in accounts payable and accruals	(4,033)	(670)
Net cash provided by (used in) operating activities	$ (14,023)	$ 4,683
CASH FLOWS FROM INVESTING ACTIVITIES:		
Short-term deposit withdrawal		$ 20,420
Purchase of property and equipment	$ (1,235)	(857)
Proceeds from sale of property and equipment		3
Amounts funded in respect of employee rights upon retirement, net	(19)	(25)
Net cash provided by (used in) investing activities	$ (1,254)	$ 19,541
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment for convertible notes redemption		$ (20,420)
Proceeds from issuance of common stock under the Sales Agreement, net	$ 6,812	—
Exercise of warrants and options	2,368	—
Net cash provided by (used in) financing activities	$ 9,180	$ (20,420)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (16)	$ (29)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(6,113)	3,775
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,760	23,634
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 13,647	$ 27,409

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, 2025	**September 30, 2024**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 230	$ 402
Exercise of options	$ 52	$ -
Operating lease right of use assets obtained in exchange for new operating lease liabilities	$ 3,104	$ 376
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Tax paid	$ 1,182	
Interest paid	$ -	$ 1,532
Interest received	$ 258	$ 1,481

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

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiary, the "Company") and its wholly-owned subsidiary, Protalix Ltd., are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company's proprietary ProCellEx® protein expression system ("ProCellEx"). To date, the Company has successfully developed two enzyme replacement therapies (ERTs); Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease and Elelyso® (taliglucerase alfa) for the treatment of adult patients and children four years of age and greater with Gaucher disease.

Elelyso was first approved by the U.S. Food and Drug Administration ("FDA") in May 2012 and is now approved for marketing in 23 markets including Brazil, Israel and others. In May 2023, both the European Commission ("EC") and the FDA announced the approval of Elfabrio, each for adult patients with a confirmed diagnosis of Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage. Elfabrio, which the Company referred to as PRX-102 during its development stage, has been approved for marketing in the United States, the European Union, Great Britain, Switzerland, Peru, Israel, Russia, Singapore, Australia and Taiwan.

The Company is committed to leveraging its record of success as the Company progresses with the development of treatments for rare and orphan diseases. In addition, the Company continuously works on the further development and enhancement of its ProCellEx technology. Accordingly, the Company is turning its focus to new, early-stage product candidates that treat indications for which there are high unmet needs in terms of efficacy and safety, including renal diseases. Treatments of interest will address both genetic and non-genetic diseases. The Company intends to use its ProCellEx platform and PEGylation capabilities, as well as other modalities such as small molecules and antibodies, to take advantage of highly innovative opportunities. The Company is also exploring novel platform technologies.

The Company continuously evaluates potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutions. Except with respect to Elfabrio and Elelyso, the Company holds the worldwide commercialization rights to its other proprietary development candidates.

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

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

(2) PRX-119, the Company's plant cell-expressed PEGylated recombinant human DNase I product candidate for long and customized systemic circulation in the bloodstream for NETs-related diseases (neutrophil extracellular traps).

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, and demonstrate the safety and efficacy of its product candidates. The Company cannot reasonably predict the outcome of these activities.

The Company, through its wholly-owned subsidiary, Protalix Ltd., has licensed the rights to commercialize Elelyso worldwide (other than Brazil) to Pfizer Inc. ("Pfizer"), and in Brazil to Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health (the "Brazilian MoH"). Elelyso is marketed as BioManguinhos alfataliglicerase in Brazil. The Company has partnered with Chiesi Farmaceutici S.p.A. ("Chiesi") for the development and commercialization of Elfabrio through two exclusive global licensing and supply agreements. On October 19, 2017, Protalix Ltd. entered into an Exclusive License and Supply Agreement with Chiesi (the "Chiesi Ex-US Agreement") pursuant to which Chiesi was granted an exclusive license for all markets outside of the United States to commercialize Elfabrio. On July 23, 2018, Protalix Ltd. entered into an Exclusive License and Supply Agreement with Chiesi (the "Chiesi US Agreement"), with respect to the commercialization of Elfabrio in the United States.

Since its approval by the FDA, Elelyso has been marketed by Pfizer in accordance with the exclusive license and supply agreement entered into between Protalix Ltd. and Pfizer, which is referred to herein as the Pfizer Agreement. In October

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

2015, Protalix Ltd. and Pfizer entered into an amended and restated exclusive license and supply agreement, which is referred to herein as the Amended Pfizer Agreement, pursuant to which the Company sold to Pfizer its share in the collaboration created under the Pfizer Agreement for the commercialization of Elelyso. As part of the sale, the Company agreed to transfer its rights to Elelyso in Israel to Pfizer while gaining full rights to it in Brazil. Under the Amended Pfizer Agreement, Pfizer is entitled to all of the revenues, and is responsible for 100% of expenses globally for Elelyso, excluding Brazil where the Company is responsible for all expenses and retains all revenues.

On June 18, 2013, the Company entered into a Supply and Technology Transfer Agreement (the "Brazil Agreement") with Fiocruz for BioManguinhos alfataliglicerase. Fiocruz's purchases of BioManguinhos alfataliglicerase to date have been significantly below certain agreed-upon purchase milestones and, accordingly, the Company has the right to terminate the Brazil Agreement. Notwithstanding the termination right, the Company is, at this time, continuing to supply BioManguinhos alfataliglicerase to Fiocruz and patients continue to be treated with BioManguinhos alfataliglicerase in Brazil.

On February 27, 2023, the Company entered into that certain At The Market Offering Agreement (as may be amended from time to time, the "Sales Agreement") with H.C. Wainwright & Co., LLC, as the Company's sales agent (the "Agent"). After giving effect to the sales under the Sales Agreement in January 2025, no shares of common stock, par value $0.001 per share (the "Common Stock"), remained available for offer and sale under the Sales Agreement. On March 17, 2025, the Company entered into an amendment to the Sales Agreement pursuant to which the Company increased the aggregate gross sales price of shares of Common Stock available for offer and sale under the Sales Agreement by $20.0 million. As of September 30, 2025, approximately $15.7 million in shares of Common Stock remain available to be sold under the Sales Agreement.

Because the Company's operations are conducted in the State of Israel, the business and operations may be directly affected by economic, political, geopolitical and military conditions in Israel. Since October 2023, following an infiltration by Hamas terrorists of Israel's southern border from the Gaza Strip and attacks on civilian and military targets, Israel has been engaged in military activity on a number of fronts, including with the Hamas in the Gaza Strip, Hezbollah in Lebanon, Iran, the Houthis terrorist group that controls parts of Yemen, and others. Such clashes may escalate in the future into a greater regional conflict. On October 9, 2025, Israel and Hamas entered into a ceasefire agreement intended to permanently end the war between Israel and Hamas. However, there are no assurances regarding continued compliance with such agreement. While the conflict created and continues to create heightened security concerns, disruptions to business operations, and economic instability within Israel, the ceasefire may contribute to improved regional stability. However, the security situation remains fluid and any renewed military actions, restrictions, or government-imposed measures could adversely affect the Company's business, operations and financial condition. The Company's facilities are deemed an "essential enterprise" which means it operates or can be operated for the purposes of state defense or public security or for the maintenance of essential supplies or services, allowing the Company to maintain operations during emergencies. The Company has elected to store manufactured drug substance in multiple locations, both within and outside of Israel, to mitigate the risk of loss. As of the issuance of these financial statements, the impact of the military action has not had an adverse effect on the Company's operations.

The Company expects to continue to incur significant expenditures in the near future due to research and developments efforts with respect to its product candidates. The Company believes that its cash and cash equivalents and short-term bank deposits as of September 30, 2025, are sufficient to satisfy the Company's capital needs for at least 12 months from the date that these financial statements are issued.

b. Basis of presentation

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

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

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2024, filed by the Company with the U.S. Securities and Exchange Commission (the "Commission") on March 17, 2025. The comparative balance sheet at December 31, 2024 has been derived from the audited financial statements at that date. There have been no material changes in our significant accounting policies as described in our consolidated financial statements for the year ended December 31, 2024.

c. Net earnings (loss) per share

Basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares of Common Stock outstanding for each period.

Diluted earnings per share is calculated by dividing the net income by the weighted-average number of shares of Common Stock outstanding during each period increased to include the number of additional shares of Common Stock that would have been outstanding if the potentially dilutive shares had been issued.

In computing diluted earnings per share, basic earnings per share are adjusted to take into account the potential dilution that could occur upon: (i) the exercise of options granted under employee stock compensation plans using the treasury stock method; (ii) the exercise of warrants using the treasury stock method; and (iii) the conversion of the convertible notes using the "if-converted" method.

d. Convertible notes

In September 2024, the Company repaid in full all of the outstanding principal and interest payable under its 7.50% Senior Secured Convertible Promissory Notes due 2024 (the "2024 Notes"). The repayment of the convertible notes at maturity was financed entirely with available cash.

Prior to January 1, 2024, the Company's outstanding 2024 Notes were accounted for as a liability (debt) and equity component (conversion option) as the Company had the option to settle such notes may be settled wholly or partly in cash.

Starting from January 1, 2024, the convertible debt instruments were accounted for as a single liability measured at amortized cost.

e. Recently issued accounting pronouncements, not yet adopted

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis with the option to apply the standard retrospectively. The Company expects the adoption of this standard to result in expanded disclosures in its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03 "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses," which requires disclosure about the types of costs and expenses included in certain expense captions presented on the income statement. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted, and may be applied either prospectively or retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

In July 2025, the FASB issued ASU 2025-05, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets. This amendment introduces a practical expedient for the application of the current expected credit loss (CECL) model to current accounts receivable and contract assets. The

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

amendments will be effective for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods, on a prospective basis, with early adoption permitted. Based on the Company's evaluation of this guidance, no material impact is expected on its consolidated financial statement disclosures.

NOTE 2 - INVENTORIES

Inventories at September 30, 2025 and December 31, 2024 consisted of the following:

(U.S. dollars in thousands)	September 30, 2025	December 31, 2024
Raw materials	$ 4,983	$ 4,549
Work in progress	5,355	11,245
Finished goods	10,917	5,449
Total inventory	$ 21,255	$ 21,243

NOTE 3 – FAIR VALUE MEASUREMENT

The Company 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 identical or close to their carrying value.

NOTE 4 – OPERATING LEASES

The Company is a party to several lease agreements for its facilities that included varying lease periods and options for extensions. The Company is currently in the second option period for each of the three leases, which periods are not uniform. In the three months ended September 30, 2025, the Company amended all of the facility leases, collectively, to provide that the third option period for each lease will end on December 31, 2031 and will be associated with a unform rent increase equal to 7.5%. Thereafter, each lease will extend automatically, on an individual basis, for up to four additional five-year periods unless the Company provides the lessor with six months' advance notice that it does not intend that any individual option extension become effective. Each option to renew a lease in each of the four option periods shall include a rent increase equal to 5% of the rent payable for the applicable previous option period. Prior to the amendment, the options to extend the leases were associated with increases of either 7.5% or 10%. The Company expects to exercise the options in future periods. As of September 30, 2025, the Company provided bank guarantees of approximately $0.6 million, in the aggregate, to secure the fulfillment of its obligations under the lease agreements.

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

The Company adjusted the operating lease right of use assets by $3.1 million reflecting the amount of remeasurement of the lease liability using a new discount rate at the amendment date.

The Company is a party to several three-year leases for vehicles which are regularly amended as new vehicles are leased.

The following table sets forth data regarding the Company's operating leases for the three and nine months ended September 30, 2024 and 2025:

(*U.S. dollars in thousands*)	Nine Months Ended September 30, 2025	2024	Three Months Ended September 30, 2025	2024
Operating lease costs	$ 1,395	$ 1,195	$ 476	$ 420
Cash paid for amounts included in the measurement of lease liabilities	1,338	1,207	457	413
Weighted average remaining lease term (in years)	22.6	6.2	22.6	6.2
Weighted average discount rate	13.4 %	12.8 %	13.4 %	12.8 %

The following table sets forth a maturity analysis of the Company's operating lease liabilities as of September 30, 2025:

(*U.S. dollars in thousands*)	September 30, 2025
First year	$ 1,397
Second year	$ 1,141
Third year	$ 1,074
Fourth year	$ 1,040
Fifth year and thereafter	$ 22,273
Total undiscounted cash flows	$ 26,925
Less: imputed interest	$ 18,748
Present value of operating lease liabilities	$ 8,177

NOTE 5 – STOCK TRANSACTIONS

a. During the nine months ended September 30, 2025, the Company issued 908,000 shares of Common Stock in connection with the exercise of warrants issued in 2020 generating proceeds equal to approximately $2.1 million from such exercises. All such exercises were effected during the first quarter of 2025 and all unexercised warrants expired on March 11, 2025. Accordingly, as of March 12, 2025, no warrants remained outstanding.

b. During the nine months ended September 30, 2025, the Company sold, in the aggregate, 2,775,215 shares of Common Stock under the Sales Agreement. The Company generated gross proceeds equal to approximately $7.0 million in connection with such sales (issuance costs were $0.2 million). All such sales were effected during the first and second quarters of 2025.

c. During the nine months ended September 30, 2025, the Company issued, in the aggregate, 248,625 shares of Common Stock in connection with the exercise of options to purchase 248,625 shares of Common Stock by certain current and former employees of the Company. The Company received cash proceeds equal to $0.2 million in connection with such exercises. All such exercises were effected during the third quarter of 2025.

d. During the three months ended September 30, 2025, the Company granted, with the approval of the Company's compensation committee, 10-year options to purchase 1,448,990 shares of Common Stock, in the aggregate, to certain of the Company's officers, directors, other employees and a consultant under the Company's Amended and Restated 2006 Employee Stock Incentive Plan, as amended (the "Plan"). The options generally vest over a three-year period in 12 equal quarterly increments. Vesting of the options granted to executive officers is subject to automatic acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan, and are subject to certain other terms and conditions. The Company estimated the aggregate fair value of the options on the applicable dates of grant

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using the Black-Scholes option-pricing model to be approximately $1.5 million using the following assumptions (weighted average): stock price equal to $1.56, exercise price equal to $1.56, dividend yield of 0%, expected volatility of 73.64%, risk-free interest rate of 3.9% and expected life in years, 5.75.

e. During the three months ended September 30, 2025, the Company granted, with the approval of the Company's compensation committee, 559,210 shares of restricted Common Stock, in the aggregate, to certain of the Company's officers, directors, other employees and a consultant under the Plan. The shares of restricted Common Stock generally vest over a three-year period in 12 equal quarterly increments, with 52,910 of such shares of restricted Common Stock fully vested upon grant (September 22, 2025). Vesting of restricted Common Stock granted to executive officers is subject to automatic acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan, and are subject to certain other terms and conditions. The Company estimated the aggregate fair value of the restricted stock on the applicable dates of grant to be approximately $0.9 million using stock prices equal to $1.64 and $1.89.

NOTE 6 – EARNINGS (LOSS) PER SHARE

Basic and diluted earnings (loss) per share attributable to common stockholders were calculated as follows:

(In thousands, except share data)	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024	Three Months Ended September 30, 2025	Three Months Ended September 30, 2024
Numerator:				
Net income (loss)	$ (1,100)	$ (3,562)	$ 2,355	$ 3,236
Add:				
Financial expenses of 2024 Notes*				(503)
Net income (loss) for diluted calculation	$ (1,100)	$ (3,562)	$ 2,355	$ 2,733
Denominator:				
Weighted average shares of Common Stock outstanding for basic calculation	78,225,112	73,301,091	79,281,685	73,549,745
Weighted average dilutive effect of 2024 Notes				7,667,323
Weighted average dilutive effect of stock options and restricted stock			1,532,879	
Weighted average shares of Common Stock outstanding for diluted calculation	78,225,112	73,301,091	80,814,564	81,217,068

* Financial expenses on 2024 Notes consists of add back of financial expense incurred during the period and inclusion of make-whole interest payments that will be incurred upon conversion.

Diluted earnings (loss) per share do not include 11,288,007 shares of Common Stock underlying outstanding stock options, unvested shares of restricted stock and warrants for the nine months ended September 30, 2025 because the effect would be anti-dilutive.

Diluted earnings (loss) per share do not include 3,745,682 shares of Common Stock underlying outstanding stock options and unvested shares of restricted stock for the three months ended September 30, 2025 because the effect would be anti-dilutive.

Diluted earnings (loss) per share do not include 30,515,287 shares of Common Stock underlying outstanding stock options, unvested shares of restricted stock, warrants and the 2024 Notes for the nine months ended September 30, 2024, and 20,173,438 shares of Common Stock underlying outstanding stock options, unvested shares of restricted stock and warrants for the three months ended September 30, 2024, because the effect would be anti-dilutive.

PROTALIX BIOTHERAPEUTICS, INC.
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NOTE 7 – TAXES ON INCOME (TAX BENEFIT)

The following table summarizes the Company's taxes on income:

	Nine Months Ended September 30,		Three Months Ended September 30,	
(U.S. dollars in thousands)	2025	2024	2025	2024
Current taxes on income	$ 91	$ 164	$ (175)	$ 164
Deferred taxes on income	177	236	$ 59	$ 443
Total taxes on income (tax benefit)	$ 268	$ 400	$ (116)	$ 607

The Company had an effective tax rate of (32)% for the nine months ended September 30, 2025 compared to an effective tax rate of (13)% for the nine months ended September 30, 2024. For the nine months ended September 30, 2025, the difference between the Company's effective tax rate and the U.S. federal statutory rate of 21% was the result of forecasted profits derived primarily from U.S. taxable GILTI income mainly due to Section 174 of the U.S. Tax Cuts and Jobs Act of 2017 (the "TCJA"), which was enacted in December 2017.

On July 4, 2025, tax reform legislation was enacted in the United States through the passage of H.R.1, One Big Beautiful Bill Act ("HR1"), which includes significant corporate tax changes, including a restoration of the current deductibility for domestic research expenditures beginning in 2025, with transition options for previously capitalized amounts.

NOTE 8 – SEGMENT INFORMATION

a. The Company operates in Israel as a single operating segment. The Company's President and Chief Executive Officer is the CODM. The CODM makes decisions on resource allocation, assesses performance of the business and monitors budget versus actual results on a consolidated basis.

b. Segment information:

	Nine Months Ended September 30,		Three Months Ended September 30,	
(U.S. dollars in thousands)	2025	2024	2025	2024
Revenues from customers	$ 43,622	$ 35,181	$ 17,851	$ 17,959
Less:				
Employee salaries and related expenses	16,502	15,091	5,853	4,734
Sub-contractors expense	9,348	6,413	1,886	1,649
Interest expense	—	1,021	—	260
Interest income	(817)	(970)	(289)	(212)
Depreciation	1,078	970	372	329
Other segment expenses*	18,343	15,818	7,790	7,356
Income (loss) before taxes on income	(832)	(3,162)	2,239	3,843
Taxes on income (tax benefit)	268	400	(116)	607
Segment net income (loss)	$ (1,100)	$ (3,562)	$ 2,355	$ 3,236

* Other expenses included in net income includes raw materials, rent and utilities and others.

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

(U.S. dollars in thousands)	Nine Months Ended September 30,		Three Months Ended September 30,	
	2025	2024	2025	2024
Gaucher disease:				
Pfizer (Ireland)	$ 15,431	$ 11,431	$ 2,805	$ 3,430
Fiocruz (Brazil)	$ 9,121	$ 9,314	$ 6,105	$ 2,048
Fabry disease:				
Chiesi (Italy)	$ 18,556	$ 14,075	$ 8,763	$ 12,361
Total revenues from selling goods	$ 43,108	$ 34,820	$ 17,673	$ 17,839
Revenues from license and R&D services	$ 514	$ 361	$ 178	$ 120

d. Long lived assets are located in Israel.

NOTE 9 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Balance sheets:

(U.S. dollars in thousands)	September 30, 2025	December 31, 2024
Accounts payable and accruals – other:		
Payroll and related expenses	$ 745	$ 1,343
Provision for vacation	2,209	1,811
Accrued expenses	8,126	9,568
Royalties payable	558	1,080
Income tax payable	2,385	3,476
Payable to customer	920	2,056
Property and equipment suppliers	230	254
	$ 15,173	$ 19,588

NOTE 10 – SUBSEQUENT EVENTS

a. Since the end of the quarter ended September 30, 2025 and through the issuance of these financial statements, the Company collected approximately $3.0 million from sales to Fiocruz (Brazil), approximately $9.9 million from sales to Chiesi and $1.4 million from sales to Pfizer.

b. Since the end of the quarter ended September 30, 2025, the Company issued, in the aggregate, 79,856 shares of Common Stock in connection with the exercise of options to purchase 79,856 shares of Common Stock by a former employee and a current employee of the Company. The Company received cash proceeds equal to approximately $94,200 in connection with such exercise.

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

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS SUMMARY

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the consolidated financial statements and the related notes included elsewhere in this Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2024. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements within the meanings of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to our company, our subsidiary or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements as a result of several factors, including those set forth in this Quarterly Report on Form 10-Q.

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

- risks related to the commercialization of Elfabrio® (pegunigalsidase alfa-iwxj), our approved product for the treatment of adult patients with Fabry disease;

- risks relating to Elfabrio's market acceptance, competition, reimbursement and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product;

- the possible disruption of our operations due to military actions conducted by Israel with the Hamas terrorist organization located in the Gaza Strip, Hezbollah and others, including as a result of the disruption of the operations of certain regulatory authorities and of certain of our suppliers, collaborative partners, licensees, clinical trial sites, distributors and customers, and the risk that the current hostilities will result in a greater regional conflict;

- risks related to the regulatory approval and commercial success of our other product and product candidates, if approved;

- risks related to our expectations with respect to the projected market of our products and product candidates;

- failure or delay in the commencement or completion of our preclinical studies and clinical trials, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to satisfactorily demonstrate non-inferiority to approved therapies; 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;

- delays in the approval or potential rejection of any applications we file with the FDA, European Medicines Agency, or EMA, or other health regulatory authorities for our other product candidates, including the requested a re-examination of the negative opinion issued by the CHMP regarding the proposed dosing regimen of 2 mg/kg body weight infused E4W for Elfabrio, and other risks relating to the review process;

- risks associated with global conditions and developments such as new or increased tariffs, new trade restrictions, supply chain challenges, the inflationary environment and tight labor market, and instability in the banking industry, which may adversely impact our business, operations and ability to raise additional financing if and as required and on terms acceptable to us;

- risks related to any transactions we may effect in the public or private equity or debt markets to raise capital to finance future research and development activities, general and administrative expenses and working capital;

- risks relating to our evaluation and pursuit of strategic partnerships;

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

- risks relating to our ability to manage our relationship with our collaborators, distributors or partners, including, but not limited to, Pfizer and Chiesi;

- risks related to the amount and sufficiency of our cash and cash equivalents and short-term bank deposits;

- risks relating to changes to interim, top-line or preliminary data from clinical trials that we announce or publish;

- risks relating to the compliance by Fiocruz with its purchase obligations under the Brazil Agreement, which may have a material adverse effect on us and may result in the termination of such agreement;

- risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector;

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

- 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;

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

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

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

- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. 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 FDA or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

Recent Company Developments

- On August 24, 2025, Gilad Mamlok succeeded Eyal Rubin as our Senior Vice President and Chief Financial Officer.

- On October 6, 2025, we submitted an Investigational New Drug (IND) application to the FDA in connection with our planned phase 2 clinical trial of PRX-115. The IND has become effective following the FDA's standard 30-day review period.

- On October 17, 2025, we announced, together with Chiesi, that the EMA's Committee for Medicinal Products for Human Use (CHMP) had issued a negative opinion on the request to approve the dosing regimen of 2 mg/kg body weight infused every 4 weeks (E4W) for Elfabrio.

- On November 3, 2025, we announced, together with Chiesi, that we have requested a re-examination of the negative opinion issued by the CHMP regarding the proposed dosing regimen of 2 mg/kg body weight infused E4W for Elfabrio.

Our Business

We are a commercial stage biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced via our proprietary ProCellEx® plant cell-based protein expression system. We are the first and only company to gain FDA approval of a protein produced through plant cell-based expression in suspension. Our unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

To date, we have successfully developed two commercial products, both of which are enzyme replacement therapies (ERTs): Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease and Elelyso® (taliglucerase alfa) for the treatment of adult patients and children four years of age and greater with Gaucher disease. Elelyso was first approved by the FDA in May 2012 and is now approved for marketing in 23 markets including Brazil, Israel and others. Elfabrio, which we referred to as PRX-102 during its development stage, has been approved for marketing in the United States, the European Union, Great Britain, Switzerland, Peru, Israel, Russia, Singapore, Australia and Taiwan. We have licensed the rights to commercialize Elelyso worldwide (other than Brazil) to Pfizer, and in Brazil to Fiocruz. Elelyso is marketed as BioManguinhos alfataliglicerase in Brazil. We have partnered with Chiesi for the development and commercialization of Elfabrio.

Our partnership with Chiesi is governed by two exclusive global licensing and supply agreements for Elfabrio for the treatment of Fabry disease with Chiesi; the Chiesi Ex-US Agreement and the Chiesi US Agreement, or collectively, the Chiesi Agreements. Under the agreements, we have received certain upfront payments and development cost reimbursements, and remain entitled to potential milestone payments and tiered payments for drug product purchased by Chiesi from Protalix Ltd. See Commercialization of Approved Products--Elfabrio (pegunigalsidase alfa/PRX-102) – Chiesi Farmaceutici.

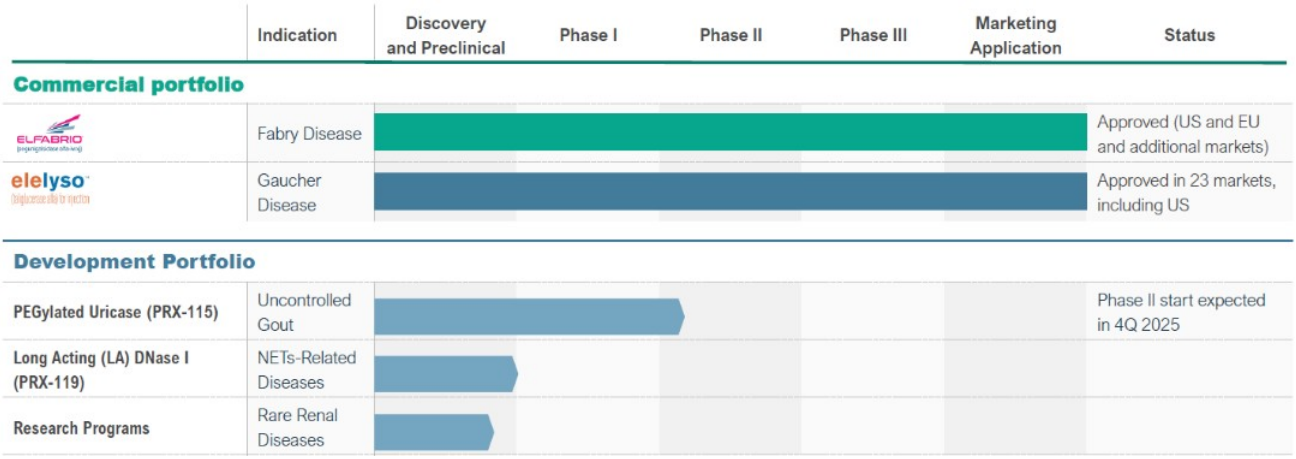
Under the terms of our agreements with Chiesi, Chiesi is solely responsible for the global commercialization and medical programs of Elfabrio, including patient acquisition and retention, and distribution of Elfabrio to patients. We are responsible for manufacturing of Elfabrio drug substance and product delivery to Chiesi. Operationally, Chiesi conducts its own internal commercial forecasting to guide inventory needs. To date, since approval in 2023, Chiesi has placed bulk orders for Elfabrio. As a result, the orders we receive from Chiesi may not be timed in relation to Chiesi's pace of patient acquisition and retention. Our sales of Elfabrio to Chiesi may not reflect patient demand for Elfabrio. In addition, on a period-to-period basis, there may be variations in the orders placed by Chiesi resulting in variability in our period-to-period results as we, in turn, recognize revenues from sales of Elfabrio upon delivery of the drug product to Chiesi. There may be periods during which no orders are placed by Chiesi, whether as a result of inventory de-stocking or other factors. We do not anticipate that these Chiesi ordering patterns will change until the demand characteristics for Elfabrio stabilize, the launch of Elfabrio matures and Elfabrio's share of the market for Fabry disease treatment grows.

Under the Amended Pfizer Agreement, we have licensed to Pfizer the global rights to market and sell Elelyso in all markets, excluding Brazil. We sell drug substance to Pfizer for the production of Elelyso, subject to certain terms and conditions and Pfizer retains the revenues generated from such sales. See Commercialization of Approved Products--Elelyso – Pfizer and --Alfataliglicerase – Fundação Oswaldo Cruz (Fiocruz).

Our sales of Elelyso to Pfizer and Fiocruz are structured in a manner similar to Chiesi. We sell the products at a fixed price directly to Pfizer and Fiocruz who maintain product in inventory, and we recognize revenue from those sales upon delivery. The timing of such sales does not directly reflect patient demand and, on a period-to-period basis, there may be variations in the orders placed by each of Pfizer and Fiocruz resulting in variability in our period-to-period results. There may be periods during which no orders are placed by either Pfizer or Fiocruz, whether as a result of inventory de-stocking or other factors.

In addition to Elelyso and Elfabrio, we are developing PEGylated uricase, or PRX-115, for the treatment of uncontrolled gout, Long Acting (LA) DNase I, or PRX-119, for the treatment of NETs-related diseases, and a number of other technologies and preclinical assets. We have completed a phase 1 First-in-Human clinical trial of PRX-115 and we are currently in the advance stages of preparations for a phase 2 clinical trial of PRX-115. We submitted an IND to the FDA in connection with the trial and it has become effective following the FDA's standard 30-day review period. We expect to initiate the trial in the fourth quarter of 2025.

Product Pipeline



Our proprietary ProCellEx platform is being used to manufacture both of our approved and marketed products as well as PRX-115 and PRX-119.

We are committed to leveraging our track record of success as we progress with the development of treatments for rare and orphan diseases. In addition, we continuously work on the further development and enhancement of our ProCellEx technology. Accordingly, we are turning our focus to new, early-stage product candidates that treat indications for which there are high unmet needs in terms of efficacy and safety, including renal diseases. Treatments of interest will address both genetic and non-genetic diseases. We intend to use our ProCellEx platform and PEGylation capabilities, as well as other modalities such as small molecules and antibodies, to take advantage of highly innovative opportunities. We are also exploring novel platform technologies.

ProCellEx: Our Proprietary Protein Expression System

ProCellEx is our proprietary platform used to produce and manufacture recombinant proteins through plant cell-based expression in suspension. We are the first and only company to receive FDA approval of a protein produced through plant cell-based expression, and with the approval of Elfabrio, we now produce two commercial proteins through our platform.

ProCellEx consists of a comprehensive set of proprietary technologies and capabilities, including the use of advanced genetic engineering and plant cell culture technology, enabling us to produce complex, proprietary, and biologically equivalent proteins for a variety of human diseases. Our protein expression system facilitates the creation and selection of high-expressing, genetically-stable cell lines capable of expressing recombinant proteins. The system plays an important role in the execution of our corporate strategy as it allows us to develop and produce tailored complex recombinant therapeutic proteins and to genetically engineer and/or chemically modify such proteins pre- and/or post-production. The engineering and modification of the therapeutic proteins have the potential to provide added clinical benefits by improving the biological characteristics (e.g., glycosylation, half-life, immunogenicity).

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

We developed ProCellEx based on our plant cell culture technology for the development, expression and manufacture of recombinant proteins that are the essential foundation of modern biotechnology. We develop new, recombinant therapeutic proteins by using the natural capability of agrobacterium to transfer a DNA fragment into the plant chromosome, allowing the genome of the plant cell to code for specific proteins of interest. The agrobacterium-mediated transformed cells are then able to produce specific proteins, which are extracted and purified and can be used as therapies to treat a variety of diseases.

Our ProCellEx technology can be utilized to express complex therapeutic proteins belonging to different drug classes, such as enzymes, hormones, monoclonal antibodies, cytokines and vaccines. The entire protein expression process, from initial nucleotide cloning to large-scale production of the protein product, occurs under Current Good Manufacturing Practice-, or cGMP-, compliant, controlled processes. Our plant cell culture technology uses cells, such as carrot and tobacco (BY-2) cells, which undergo advanced

genetic engineering and/or chemical modifications, and are grown on an industrial scale in a disposable, flexible bioreactor system. Our system does not involve mammalian or animal-derived components or transgenic field-grown or whole plants at any point in the production process.

Cell growth, from initiating scale-up steps from a cell-bank through large-scale production takes place in a clean-room environment in flexible, sterile, custom-designed polyethylene bioreactors, and does not require the use of large stainless-steel bioreactors commonly used in mammalian-based systems for recombinant protein production. The ProCellEx reactors are easy to use and maintain, allow for rapid horizontal scale-up and do not involve the risk of mammalian viral contamination. Our bioreactors are well-suited for plant cell growth using a simple, inexpensive, chemically defined growth medium. The reactors, which are custom-designed and optimized for plant cell cultures, require low initial capital investment and are rapidly scalable at a low cost.

In addition, we continuously work on the further development and enhancement of our ProCellEx technology.

Our Marketed Products

We have two commercial products, each of which is an ERT; Elelyso and Elfabrio.

Elelyso for the Treatment of Gaucher Disease

Elelyso (taliglucerase alfa), our first commercial product, was approved by the FDA in 2012 for injection as an ERT for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. In August 2014, the FDA approved Elelyso for injection for children four years of age and greater. Elelyso is the first plant cell derived recombinant protein to be approved by the FDA for the treatment of Gaucher disease and is now approved in 23 markets including the United States, Brazil, Israel and others.

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

The global market for Gaucher disease, that includes Sanofi's Cerezyme®, Shire's (acquired by Takeda Pharmaceutical Company Limited) Vpriv® and Sanofi's Cerdelga®, among others, was $1.7 billion in 2024, is forecasted to be approximately $1.7 billion in 2025 and is forecasted to grow at a compound annual growth rate (CAGR) of approximately -1.82% from 2024-2030.

The current standard of care for Gaucher disease is ERT, which is a medical treatment where recombinant enzymes are injected into patients to replace the lacking or dysfunctional enzyme. In Gaucher disease, recombinant GCD is infused to replace the mutated or deficient natural GCD enzyme. Elelyso is the only alternative ERT treatment of Gaucher disease to Cerezyme and Vpriv.

Elfabrio for the Treatment of Fabry Disease

Elfabrio, our second commercial product, was approved by the EC for marketing in the EU and by the FDA for marketing in the United States in May 2023 for adult patients with Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage. According to the EMA, overall, the benefit/risk balance of Elfabrio is positive in the claimed indication (Fabry disease). Similarly, the FDA review team concluded that in the context of Fabry disease as a rare, serious disease with limited therapeutic options that may not be suitable to all individual patients, the benefit-risk of Elfabrio is favorable for the treatment of adults with confirmed Fabry disease. The FDA noted its determination that substantial evidence of effectiveness for Elfabrio in Fabry patients was established with one adequate and well-controlled study, our phase 1/2 clinical trial of Fabry disease, with confirmatory evidence provided by the *BALANCE* study. The FDA review team also concluded that the *BALANCE* study met its primary efficacy endpoint, which assessed the annualized rate of change in eGFR (estimated glomerular filtration rate) over 104 weeks. However, the FDA also determined that the results from the *BALANCE* study did not support a non-inferiority claim to the comparator product due to the lack of data to support the non-inferiority margin.

Since the approvals by the FDA and the EMA, Elfabrio has been approved for marketing in Great Britain, Switzerland, Peru, Israel, Russia, Singapore, Australia and Taiwan for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease.

Fabry disease is a serious life-threatening rare genetic disorder. Fabry patients lack or have low levels of α-galactosidase-A resulting in the progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide, or Gb_3, in blood vessel walls throughout their body. The ultimate consequences of Gb_3 deposition range from episodes of pain and impaired peripheral sensation to end-organ failure, particularly of the kidneys, but also of the heart and the cerebrovascular system. Fabry disease occurs in one person per 40,000 to 60,000 males.

The standard of care for Fabry disease is ERT. Currently, the marketed ERTs for Fabry disease are agalsidase alfa and agalsidase beta, and now Elfabrio. Through an ERT, the missing α-galactosidase-A is replaced with a recombinant form of the protein via intravenous, or IV, infusion once every two weeks. Fabry disease, if left untreated, will progress from a less severe condition to a more serious one. It can have a significant impact on quality of life due to presence of serious, chronic and debilitating complications, including cardiovascular and renal complications, and comorbid conditions such as pain can have a significant impact on the psychological well-being of Fabry patients and their social functioning. Fabry disease involves substantial reduction in life expectancy. Causes of death are most often cardiovascular disease and, to a lesser extent, cerebrovascular disease and renal disease. The life expectancy of Fabry patients is significantly shorter compared to the general population. Untreated male Fabry patients may experience shortened lifespans to approximately 50 years, and 70 years for untreated female patients with Fabry disease. This represents a 20- and 10-year reduction of their respective lifespans.

The global market for Fabry disease, that includes agalsidase beta, Sanofi's Fabrazyme®, agalsidase alfa, Shire's Replagal® and Amicus Therapeutics' Galafold®, among others, is forecasted to be approximately $2.2 billion in 2025 and is forecasted to grow at a CAGR of 8.19% from 2024-2030 reaching approximately $3.4 billion in annual sales in 2030.

Regulatory Background of Elfabrio

On November 9, 2022, we, together with Chiesi, resubmitted to the FDA a BLA for PRX-102, the name we assigned to Elfabrio internally prior to its approvals, for the potential treatment of adult patients with Fabry disease. The initial BLA for PRX-102 was submitted to the FDA in May 2020. However, in April 2021, the FDA issued a CRL in response thereto. No concerns relating to the potential safety or efficacy of PRX-102 in the submitted data package were raised in the CRL. The FDA noted in the CRL that an inspection of our manufacturing facility in Carmiel, Israel, including the FDA's subsequent assessment of any related FDA findings, was required before the FDA can approve a new drug. Due to travel restrictions during the COVID-19 pandemic, the FDA was unable to conduct the required pre-approval inspection during the review cycle. In addition to the foregoing, the FDA noted that agalsidase beta had recently been converted to full approval, a change in regulatory circumstances which had to be addressed in the resubmitted BLA for PRX-102.

The PRX-102 MAA was submitted to the EMA in February 2022 after a meeting we held, together with Chiesi, with the Rapporteur and Co-Rapporteur of the EMA regarding PRX-102. In February 2023, we, together with Chiesi, announced that the CHMP had adopted a positive opinion, recommending marketing authorization for PRX-102. As disclosed above, Elfabrio was subsequently approved by the EC for marketing in the EU and in the United States in May 2023 for adult patients with Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage. Elfabrio was approved by the FDA with a boxed warning for hypersensitivity reactions/anaphylaxis, consistent with ERT class labeling, and warnings/precautions providing guidance on the signs and symptoms of hypersensitivity and infusion-associated reactions seen in the clinical studies as well as treatments to manage such events should they occur. The warnings/precautions for membranoproliferative glomerulonephritis (MPGN) alert prescribers to the possibility of MPGN and provide guidance for appropriate patient management. Overall, the FDA review team concluded that in the context of Fabry disease as a rare, serious disease with limited therapeutic options that may not be suitable to all individual patients, the benefit-risk of Elfabrio is favorable for the treatment of adults with confirmed Fabry disease.

In December 2024, the EMA validated Chiesi's Variation Submission for PRX-102. The Variation Submission sought to add an additional dose and dosing regimen, 2 mg/kg body weight administered every four weeks in adult patients with Fabry disease, to the current Elfabrio label. In October 2025, the CHMP issued a negative opinion regarding the submission. In November 2025, Chiesi requested a re-examination of the negative opinion.

Key Trials and Design

Our PRX-102 clinical development program was designed to show that PRX-102 has a potential clinical benefit in all adult Fabry patient populations when compared to the then marketed Fabry disease enzymes, agalsidase beta and agalsidase alfa. In preclinical studies, PRX-102 showed significantly longer half-life due to higher enzyme stability, enhanced activity in Fabry disease affected organs leading to reduction of the accumulated substrate and reduced immunogenicity, which together can potentially lead to improved efficacy through increased substrate clearance and significantly lower formation of anti-drug antibodies, or ADAs.

The phase 3 clinical program included three individual studies; the *BALANCE* study, the *BRIDGE* study and the *BRIGHT* study. In the phase 3 clinical program overall, two potential dosing regimens for PRX-102 were analyzed; 1 mg/kg every two weeks, with the potential for improved efficacy and safety offering a potential alternative to existing enzyme replacement therapies, and 2 mg/kg every four weeks. The phase 3 program was preceded by the phase 1/2 clinical trial, a dose range finding study in ERT-naïve adult patients with Fabry disease.

Phase 3 BALANCE Study

The *BALANCE* study (PB-102-F20, NCT02795676) was a pivotal 24-month, randomized, double blind, active control study of PRX-102 in adult Fabry patients with deteriorating renal function designed to evaluate the safety and efficacy of 1 mg/kg of PRX-102 administered every two weeks compared to agalsidase beta. The Clinical Study Report for the *BALANCE* study, completed in July 2022, demonstrated a favorable tolerability profile. A total of 78 patients who were previously treated with agalsidase beta for at least one year with an eGFR slope at screening worse than -2 mL/min/1.73 m^2/year were enrolled in the study. Patients were randomized on a 2:1 ratio for switching to PRX-102 or continuing on agalsidase beta. A total of 77 patients were treated; 52 with PRX-102 and 25 with agalsidase beta. Approximately 40% of the enrolled patients were female.

Forty-seven (90.4%) patients in the PRX-102 arm experienced at least one treatment-emergent adverse event (TEAE) compared to 24 (96.0%) in the agalsidase beta arm. The number of events adjusted to 100 years of exposure was 572.36 events for the PRX-102 arm and 816.85 events for the agalsidase beta arm.

TEAEs were reported for 21 (40.4%) patients in the PRX-102 arm compared to 11 (44.0%) in the agalsidase beta arm. The number of treatment-related events adjusted to 100 years of exposure is 42.85 events for the PRX-102 arm and 152.91 events for the agalsidase beta arm.

Usage of infusion pre-medication was tapered down during the study, if possible, for all patients. At baseline, 21 (40.4%) patients in the PRX-102 arm used infusion premedication compared to 16 (64.0%) in the agalsidase beta arm. At the end of the study, only three out of 47 (6.4%) patients in the PRX-102 arm used infusion premedication compared to three out of 24 (12.5%) in the agalsidase beta arm. Even with this reduction in use of premedication, there were fewer reported infusion-related reactions with PRX-102: 11 (21.2%) patients in the PRX-102 arm experienced a total of 13 events compared to six (24.0%) patients experiencing a total of 51 events in the agalsidase beta arm. The number of infusion-related reactions adjusted to 100 infusions is 0.5 for the PRX-102 arm and 3.9 for agalsidase beta arm.

Assessment of immunogenicity, that is, the existence and development of anti PRX-102 antibodies or anti-agalsidase beta antibodies, in the study indicated that for the PRX-102 arm, 18 (34.6%) patients were ADA positive at baseline, of which 17 (94.4%) had neutralizing antibody activity. For the agalsidase beta arm, eight (32.0%) patients were ADA positive at baseline, of which seven (87.5%) had neutralizing antibody activity. Only a small number of patients showed treatment-emergent ADA. At the end of the two-year study, 11 (23.4%) patients that received PRX-102 were ADA positive, of which seven (63.6%) had neutralizing antibody activity, while in the agalsidase beta arm six (26.1%) were ADA-positive and all six (100%) had neutralizing antibody activity. There was little change in the percentage of patients who were ADA positive, with a trend of reduction observed in the PRX-102 arm and stability in the agalsidase beta arm. The proportion of patients with neutralizing ADA decreased in the PRX-102 arm while it remained stable in the agalsidase beta arm.

Out of the 78 randomized patients, six patients discontinued the study: out of the five (9.4%) from the PRX-102 arm, one patient withdrew consent prior to the first infusion, two discontinued due to personal reasons, and two due to adverse events (one due to an unrelated adverse event and one due to a treatment related adverse event); one (4%) patient from the agalsidase beta arm discontinued for personal reasons. There were no deaths in this study.

Considering that in the trial patients in the PRX-102 arm were exposed for the first time to the novel enzyme, tolerability data appear favorable for PRX-102 and in-line with what was observed in the previous clinical studies of PRX-102.

The results of the direct, blinded comparison of PRX-102 to agalsidase beta, for the primary efficacy renal endpoints (i.e., eGFR change, eGFR slope) and for the main secondary endpoints (e.g., urine protein to creatinine ratio [UPCR] LVMI, MSSI, BPI) strongly suggest comparability in treatment effects between the two treatments.

At the same time, a potentially favorable safety profile was identified based on lower rates of IRR, lower ADA positivity, and less premedication use in the PRX-102 arm compared to agalsidase beta. Overall, a positive benefit-risk balance was confirmed.

Phase 3 BRIDGE Study

The *BRIDGE* study (PB-102-F30, NCT03018730) was a 12-month open-label, single arm switch-over study evaluating the safety and efficacy of PRX-102, 1 mg/kg infused every two weeks, in up to 22 Fabry patients previously treated with agalsidase alfa for at least two years and on a stable dose for at least six months. In the study, patients were screened and evaluated over three months while continuing agalsidase alfa treatment.

Final results of the data generated in the *BRIDGE* study showed substantial improvement in renal function as measured by mean annualized eGFR slope in both male and female patients. Twenty of 22 patients completed the 12-month treatment duration. In the study, the mean annualized eGFR slope of the study participants improved from -5.90 mL/min/1.73m^2/year while on agalsidase alfa to -1.19 mL/min/1.73m^2/year on PRX-102 in all patients. Male patients improved from -6.36 mL/min/1.73m^2/year to -1.73mL/min/1.73m^2/year and female patients improved from -5.03 mL/min/1.73m^2/year to -0.21 mL/min/1.73m^2/year. Following the switch to PRX-102, there was a decrease in patients with progressing or fast progressing kidney disease which is consistent with the therapeutic goals for Fabry disease, as identified by Christoph Wanner, et. al., in 2019, and most patients achieved a stable status post-switch.

PRX-102 was well-tolerated in the *BRIDGE* study, with all adverse events being transient in nature without sequelae. The majority of TEAEs were mild or moderate in severity, with two patients (9.1%) withdrawing from the therapy due to hypersensitivity reaction that was resolved. The most common moderate TEAEs were nasopharyngitis, headache and dyspnea. An immunogenicity assessment indicated that four out of 20 patients (20%) developed persistent ADAs over the course of the study, of which two had neutralizing activity.

Phase 3 BRIGHT Study

The *BRIGHT* study (PB-102-F50, NCT03180840) was a multicenter, multinational open-label, switch-over study designed to evaluate the safety, efficacy and pharmacokinetics of treatment with 2 mg/kg of PRX-102 administered every four weeks for 52 weeks (a total of 14 infusions). The 2 mg/kg every four weeks dosage has not been approved by the EMA, FDA or any other jurisdiction.

Enrollment in the study included 30 adult patients (24 males and 6 females) with mean (SD) age of 40.5 (11.3) years, ranging from 19 to 58 years previously treated with a commercially available ERT (agalsidase beta or agalsidase alfa) for at least three years and on a stable dose administered every two weeks. To determine eligibility for participation in the study, candidates were screened to identify and select Fabry patients with clinically stable kidney disease. The most common Fabry disease symptoms at baseline were acroparesthesia, heat intolerance, angiokeratomas and hypohydrosis. Patients who matched the criteria were enrolled in the study and switched from their current treatment of IV infusions every two weeks to 2 mg/kg of PRX-102 every four weeks for 12 months. Patients participating in the study were evaluated, among other disease parameters, to determine if their kidney disease had not further deteriorated while being treated with the four-week dosing regimen as measured by eGFR and for lyso-Gb_3 levels as a Fabry biomarker, as well as other parameters. In addition, participating patients were evaluated to assess the safety and tolerability of PRX-102.

The final results from the *BRIGHT* study indicate that 2 mg/kg of PRX-102 administered by intravenous infusion every four weeks was well tolerated, and Fabry disease assessed by eGFR slope and plasma lyso-Gb_3 was stable throughout PRX-102 treatment in adult Fabry patients. None of the patients without ADAs at screening developed treatment-induced ADAs following the switch to PRX-102 treatment.

All 30 patients received at least one dose of PRX-102, and 29 patients completed the one-year study. Of these 29 patients, 28 received the intended regimen of 2 mg/kg every four weeks throughout the entire study, while one patient was switched to 1 mg/kg PRX-102 every two weeks per protocol at the 11th infusion. One patient withdrew from the study after the first infusion due to a traffic accident.

Overall, 33 of 183 total TEAEs reported in nine (30.0%) of the patients were considered treatment related; all were mild or moderate in severity and the majority were resolved at the end of the study. There were no serious or severe treatment-related TEAEs and no TEAEs led to death or study withdrawal. Of the treatment-related TEAEs, 27 were infusion-related reactions (IRRs) and the remainder were single events of diarrhea, erythema, fatigue, influenza-like illness, increases urine protein/creatinine ratio, and urine positive for white blood cells. The 27 IRRs were reported in five (16.7%) patients, all male. All IRRs occurred during the infusion or within two hours post-infusion; no events were recorded between two and 24 hours post-infusion.

Study outcome measures show that plasma lyso-Gb_3 concentrations remained stable during the study with a mean change (±SE) of 3.01 nM (0.94) from baseline (19.36 nM ±3.35) to Week 52 (22.23 ±3.60 nM). Mean absolute eGFR values were stable during the 52-week treatment period, with a mean change from baseline of -1.27 mL/min/1.73 m^2 (1.39). Mean (SE) eGFR slope, at the end of the study, for the overall population, was -2.92 (1.05) mL/min/1.73 m^2/year indicating stability.

The study suggests that Fabry patients who are currently receiving ERT every two weeks may be successfully transitioned to PRX-102 2 mg/kg every four weeks as an effective and tolerable alternative treatment option.

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

Phase 1/2 Study

The phase 1/2 clinical trial of PRX-102 (NCT01678898) was a worldwide, multi-center, open-label, dose ranging study designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and efficacy parameters of PRX-102 in adult patients with Fabry disease. It was completed in 2015.

Sixteen adult, naïve Fabry patients (9 male and 7 female) completed the phase I/II study, each in one of three dosing groups, 0.2 mg/kg, 1 mg/kg and 2 mg/kg. Each patient received IV infusions of PRX-102 every two weeks for 12 weeks, with efficacy follow-up after six-month and twelve-month periods. The overall results demonstrate that PRX-102 reaches the affected tissue and reduces kidney Gb_3 inclusions burden and lyso-Gb_3 in the circulation. A high correlation was found between the two Fabry disease biomarkers, reduction of kidney Gb_3 inclusions and the reduction of plasma lyso-Gb_3 over six months of treatment.

Data was recorded at 24 months from 11 patients who completed 12 months of the long-term open-label extension trial that succeeded the phase I/II study. Patients who did not continue in the extension trial included female patients who became or planned to become pregnant and therefore were unable to continue in accordance with the study protocol and patients who relocated to a location where treatment was not available under the clinical study.

Results show that lyso-Gb_3 levels decreased approximately 90% from baseline. Renal function remained stable with mean eGFR levels of 108.02 and 107.20 at baseline and 24 months, respectively, with a modest annual eGFR slope of -2.1. An improvement across all the gastrointestinal symptoms evaluated, including severity and frequency of abdominal pain and frequency of diarrhea, was noted. Cardiac parameters, including LVM, LVMI and EF, remained stable with no cardiac fibrosis development detected. In conclusion, an improvement of over 40% in disease severity was shown as measured by the Mainz Severity Score Index, or MSSI, a score compiling the different elements of the disease severity including neurological, renal and cardiovascular parameters. In addition, an improvement was noted in each of the individual parameters of the MSSI.

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

Extension Studies

Two long-term open-label extension studies were available for patients who completed the *BALANCE*, *BRIDGE* and *BRIGHT* studies, and the extension of the phase 1/2 study. Overall, 126 patients who participated in our PRX-102 clinical program initially opted, with the advice of the treating physician, to enroll in one of the extension studies: 97 patients in the 1 mg/kg every two weeks extension study (PB-102-F60, NCT03566017) (10 patients who completed an extension study from the phase 1/2 study, 18 patients who completed the *BRIDGE* study; 69 patients who completed the *BALANCE* study), and 29 patients who completed the *BRIGHT* study in the 2 mg/kg every four weeks extension study (PB-102-F51, NCT03614234). Two of the patients in the 2 mg/kg every four weeks extension study were treated with 1 mg/kg every two weeks.

After the approval of Elfabrio in the US and the EU, sponsorship and administration of the extension studies was transferred to Chiesi. Over time, and as Elfabrio is approved for marketing in different jurisdictions, patients switch-out of the open-label extension studies. Most of them have transferred to a commercial setting; others withdraw for other reasons. Accordingly, the 1 mg/kg every two weeks dosage extension study is now closed as most patients have transferred to commercial or expanded access programs. In addition, the

US-based patients that enrolled in the 2 mg/kg every four weeks dosage extension study are now being treated with Elfabrio on a commercial basis; EU-based patients remain on the extension study.

Pediatric FLY Study

Chiesi is sponsoring, with our collaborative efforts, a clinical trial entitled "Multi-Centre, Open-label Trial to Assess the Safety, Pharmacodynamics, Efficacy and Pharmacokinetics of pegunigalsidase alfa in Patients From 2 Years to Less Than 18 Years of Age With Confirmed Fabry Disease" (NCT06328608). Recruitment has commenced. The design of the study is based on the Initial Pediatric Study Plan (iPSP) agreed to with the FDA and the paediatric investigation plan (PIP) for Elfabrio, which has been accepted, as amended, by the Paediatric Committee (PDCO) of the EMA.

Japanese RISE Study

Chiesi is currently recruiting patients for its clinical trial entitled "A Multicenter Open-Label Study to Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Pegunigalsidase Alfa (PRX-102) in Japanese Patients With Fabry Disease," or the *RISE* study (NCT05710692). The aim of the *RISE* study is to evaluate the safety and efficacy of pegunigalsidase alfa in Japanese patients (adults and adolescents) affected by Fabry disease. It is planned that a total of approximately 18-20 male and female Fabry disease patients between the ages of 13 and 60 years will be enrolled in the study which is being conducted in Japan. The study involves both the 1 mg/kg every two weeks and the 2 mg/kg every four weeks dosage regimens.

Commercialization of Approved Products

Elelyso – Pfizer

We have licensed to Pfizer the global rights to market and sell Elelyso in all markets, excluding Brazil, pursuant to the Amended Pfizer Agreement. 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 for a fixed cost, subject to certain terms and conditions, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods, subject to certain terms and conditions. In a subsequent amendment, we agreed that after the completion of the first 10-year supply period, the supply term would automatically extend for a five-year period. Any failure to comply with our supply commitments may subject us to substantial financial penalties. The Amended Pfizer Agreement includes customary provisions regarding cooperation for regulatory matters, patent enforcement, termination, indemnification and insurance requirements. We retain distribution rights to taliglucerase alfa in Brazil.

Alfataliglicerase – Fundação Oswaldo Cruz (Fiocruz)

Elelyso, marketed as BioManguinhos alfataliglicerase in Brazil, is commercialized in Brazil through the Brazil Agreement with Fiocruz, which became effective in January 2014. Gaucher patients in Brazil are entitled to receive ERT paid for by the Brazilian MoH. The Brazilian MoH clinical treatment guidelines (PCDT) state that BioManguinhos alfataliglicerase is the therapy of choice for newly diagnosed patients. BioManguinhos alfataliglicerase is currently estimated to be used by approximately 25% of Gaucher patients in Brazil.

The Brazil Agreement provides for a staged technology transfer which is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high-quality, and cost-effective supply of BioManguinhos alfataliglicerase. Fiocruz has not satisfied certain purchase commitments under the Brazil Agreement. We have continued to sell BioManguinhos alfataliglicerase for a fixed price through purchase orders. We, on a continuous basis, discuss with Fiocruz potential steps to maximize sales of BioManguinhos alfataliglicerase sales to the Brazilian MoH.

Elfabrio (pegunigalsidase alfa/PRX-102) – Chiesi Farmaceutici

Under the Chiesi Agreements, Protalix Ltd. has received $50.0 million in upfront payments and development cost reimbursements of $45 million, and is entitled to more than $1.0 billion in potential milestone payments and tiered payments for drug product purchased from Protalix Ltd. equal to 15% - 35% (ex-US) and 15% - 40% (US), depending on the amount of annual net sales in the applicable territories.

Under the Chiesi Ex-US Agreement, we granted to Chiesi an exclusive license for all markets outside of the United States to commercialize PRX-102. Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of the agreement, and Protalix Ltd. was entitled to additional payments of up to $25.0 million in development costs in the aggregate, capped at $10.0 million per year. Protalix Ltd. is also eligible to receive additional payments of up to a maximum of $320.0 million, in the

aggregate, in regulatory and commercial milestone payments. Protalix Ltd. agreed to manufacture all of the PRX-102 needed for all purposes under the agreement, subject to certain exceptions, and Chiesi will purchase PRX-102 from Protalix Ltd., subject to certain terms and conditions. Chiesi is required to make tiered payments of 15% to 35% of the net sales of the drug product in each applicable territory as consideration for the supply of PRX-102.

The exclusive license to develop and commercialize PRX-102 in the United States was granted to Chiesi under the Chiesi US Agreement. Protalix Ltd. received an upfront, non-refundable, non-creditable payment of $25.0 million from Chiesi and was entitled to additional payments of up to a maximum of $20.0 million to cover development costs for PRX-102, capped at $7.5 million per year. Protalix Ltd. is also eligible to receive additional payments of up to a maximum of $760.0 million, in the aggregate, in regulatory and commercial milestone payments. Chiesi agreed to make tiered payments of 15% to 40% of the net sales of the drug product in as consideration for product supply.

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

On August 29, 2022, we entered into a Fill/Finish Agreement, or the F/F Agreement, and a Letter Agreement, or the Letter Agreement, in each case with Chiesi. Under the F/F Agreement, we agreed to supply Chiesi with drug substance for PRX-102 and, following relevant technology and technical information transfer activities, Chiesi has agreed, among other things, to provide us with commercial fill/finish services for PRX-102, including to support the anticipated global launch of PRX-102. The Letter Agreement changed the obligations of both us and Chiesi under the Chiesi Agreements with respect to, among other things, the evaluation, selection and establishment of an initial alternate source of commercial fill/finish services for PRX-102. In addition, the Letter Agreement amended certain provisions of the Chiesi Agreements to reflect the appointment of Chiesi as a supplier to our company of commercial fill/finish services and the potential establishment of an initial alternate source of commercial fill/finish services. Subsequently, in November 2024, we amended the agreement to provide that a different Chiesi facility may act as a secondary supplier of such services and that the F/F Agreement shall have an initial term of 10 years, unless terminated earlier in accordance with the terms of the F/F Agreement. Prior to expiration of the initial term, the term may be extended by mutual agreement for an additional period of seven years upon mutual written agreement.

Product Development Pipeline

Our corporate strategy includes development of treatments for rare and orphan diseases. To execute on the strategy, we are turning our focus to new, early-stage product candidates that treat indications for which there are high unmet needs in terms of efficacy and safety, including renal diseases. Treatments of interest will address both genetic and non-genetic diseases. We intend to use our ProCellEx platform and PEGylation capabilities, as well as other modalities such as small molecules and antibodies, to take advantage of highly innovative opportunities. Our current pipeline of product candidates includes PEGylated uricase for the treatment of uncontrolled gout, Long Acting (LA) DNase I for the treatment of NETs and other technologies and preclinical assets.

PEGylated Uricase (PRX-115)

PRX-115 is our recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme under development for the potential treatment of patients with uncontrolled gout. The uricase enzyme, which does not exist naturally in humans, converts urate to allantoin, which is easily eliminated through urine. This recombinant enzyme, expressed via our ProCellEx system, is designed to lower urate levels and improve clinical manifestation of the disease while having low immunogenicity and increased half-life of the drug in the blood. Pre-clinical data demonstrates long half-life, reduced immunogenic risk and high specific activity supports the potential of PRX-115 to be a safe and effective treatment for patients with gout. One-month multiple dosing toxicity studies in two animal species and a six-month multiple dosing toxicity study in one animal species were conducted to support single- and multiple-dose studies in humans.

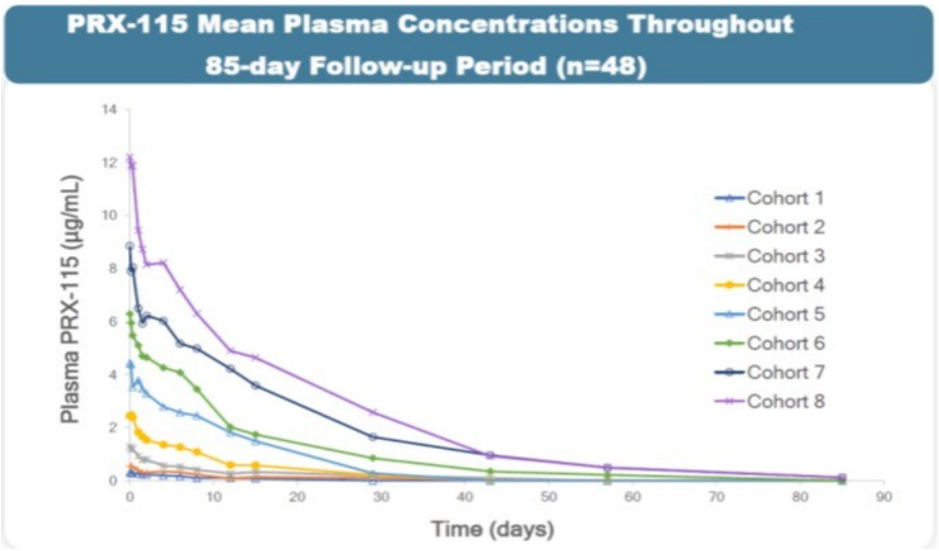
We have completed a phase 1 clinical trial of PRX-115 for the potential treatment of uncontrolled gout entitled “A Double-blind, Placebo-controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Properties of PRX-115 in Adult Volunteers With Elevated Uric Acid Levels” (NCT05745727), or the *FIH* study. The study was conducted at New Zealand Clinical Research (NZCR) under the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) and the Health and Disability Ethics Committee (HDEC) guidelines. The completed study included eight sequential dosing cohorts, each composed of eight subjects (six active and two placebo), a 3:1 ratio. Subjects in each cohort, males and females aged 18 through 65, received a single dose of PRX-115 and were analyzed for safety, pharmacokinetics (PK), pharmacodynamics (PD)

(concentrations of plasma urate) and immunogenicity for 85 days. Overall, 64 randomized subjects were enrolled across the eight cohorts; 48 subjects were treated with PRX–115 and 16 subjects were treated with placebo.

Key results from the full *FIH* study are as follows:

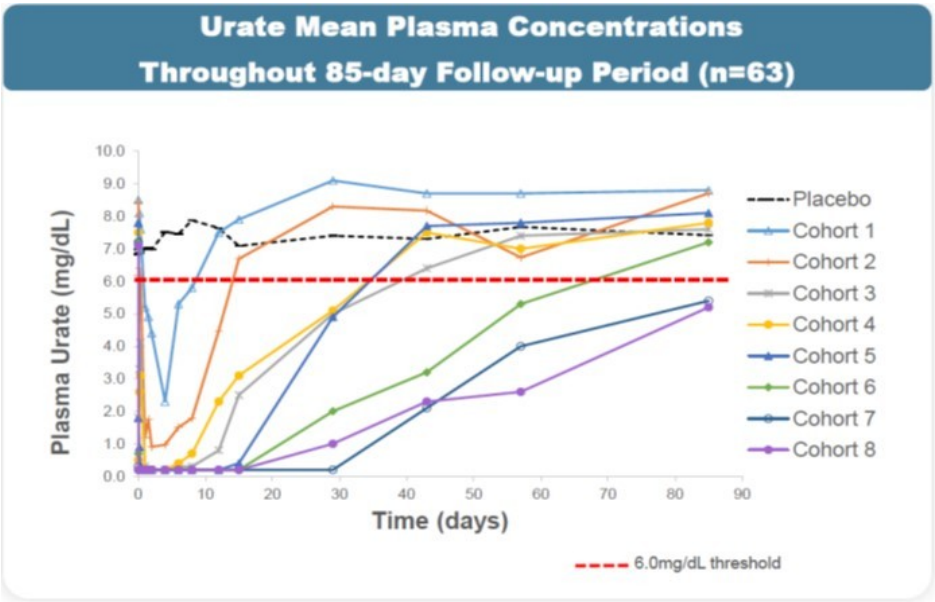
- Exposure to PRX-115 increased in a dose-dependent manner. Detectable PRX-115 levels were observed in plasma for up to 12 weeks from subjects in cohorts 6, 7, and 8. See Figure 1.

Figure 1



- In all tested doses, a single dose of PRX-115 rapidly reduced plasma urate levels. The effect and duration of response were found to be dose dependent. Following a single dose, mean plasma urate levels remained below 6.0 mg/dL for up to 12 weeks at the highest doses. See Figure 2.

Figure 2



- All randomized participants completed the study. PRX-115 was found to be well-tolerated. See Figure 3.

Figure 3. Overall Summary of Adverse Events*

	Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5	Cohort 6	Cohort 7	Cohort 8	Pooled PRX-115	Pooled Placebo
N	6	6	6	6	6	6	6	6	48	16
TEAE n(%)	5(83.3)	6(100.0)	5(83.3)	3(50.0)	6(100.0)	5(83.3)	3(50.0)	4(66.7)	37(77.1)	13(81.3)
Related TEAE n(%)	1(16.7)	5(83.3)	3 (50.0)	1(16.7)	1(16.7)	0	0	1(16.7)	12(25.0)	3(18.8)
Serious Related TEAE n(%)	0	1(16.7)	0	0	0	0	0	0	1(2.4)	0
TEAE Leading to Study Drug Discontinuation n(%)	0	1(16.7)	0	0	0	0	0	0	1(2.1)	0
TEAE Leading to Study Discontinuation n(%)	0	0	0	0	0	0	0	0	0	0

*Number of subjects reporting at least one adverse event.

Only 25% of the subjects treated with PRX-115 in the study (12/48) having reported study drug-related adverse events. The majority of such adverse events were mild to moderate and transient in nature. One subject experienced an anaphylactic reaction in cohort 2 immediately following the commencement of the infusion (6 minutes) and, accordingly, was exposed to approximately 5% of the applicable PRX-115 dose. The reaction resolved completely and the subject continued in the study for follow-up safety assessments. Premedication with anti-histamines and steroids were administered to all subjects following the anaphylaxis event. No other subjects experienced a similar reaction and no other serious adverse events were reported in the study. No related adverse events were reported for subjects treated in cohorts 6 and 7, and only for one patient per cohort in cohorts 4, 5 and 8. Approximately 50% of the subjects developed ADAs. The incidence of ADAs showed a negative relationship with the applicable PRX-115 dose, with the highest incidence observed in Cohort 1 and lower incidences in the higher PRX-115 dose cohorts.

These results suggest that PRX-115 has the potential to be a promising treatment option for patients with gout. The results demonstrate that PRX-115 may offer an effective urate-lowering treatment with an added benefit of a potentially wide dosing interval, which may enhance patient compliance and treatment flexibility. Further studies are needed to confirm the long-term safety and efficacy of PRX-115 in the gout patient population.

We have initiated preparations for a phase 2 clinical trial of PRX-115, and the IND we submitted in connection with the phase 2 trial has become effective following the FDA's standard 30-day review period. We expect to commence the study in the fourth quarter of 2025.

Gout is the most common inflammatory arthritis, affecting an estimated 14.9 million adults in the United States alone. Based on market research we have commissioned, we estimate that approximately 25% of the gout population in the US and Western Europe do not have their gout controlled. Some of those patients cannot be treated with existing therapies; others stop treatment with existing therapies due to adverse events. In addition, such research shows that there are gout patients treated with existing therapies that continue to suffer from tophi despite having reached urate target levels. The risk of gout increases with age, and is more common in males. Gout results from sustained elevation of serum urate levels (hyperuricaemia). Urate levels may increase due to diet, genetic predisposition and environmental factors leading to the deposition of monosodium urate crystals and/or tophi in joints, tendons and other tissues, which triggers recurrent episodes of pronounced acute inflammation, known as gout flares. Gout leads to substantial morbidity, severe pain, reduced quality of life, decreased physical function, increased healthcare costs, and lost economic productivity. Furthermore, gout is strongly associated with a number of comorbidities, including hypertension, cardiovascular disease, renal impairment, diabetes, obesity, hyperlipidaemia and frequently occurs in a combination known as the metabolic syndrome.

Uncontrolled gout is when serum urate (sUA) levels are above the maximum medically appropriate level (6.8 mg/dL), as well as tophi formation and/or flares that cannot be treated with available urate lowering therapies. Currently available ULTs can be effective in treating gout. However, factors such as low adherence, under dosing, disease progression that causes high patient burden or patients that are not suitable for available therapy, require new, effective and safe therapies to treat these underserved uncontrolled gout patients.

To date, two variants of recombinant uricases are approved for marketing: (i) Krystexxa® (pegloticase) for treatment of chronic gout refractory to conventional therapy (gout patients who have contraindication/failure of other lowering urate treatments) and (ii) Elitek®, indicated for the treatment of tumor lysis syndrome but not gout. Both have a black box warning for anaphylaxis and other major side-effects. The FDA label of Krystexxa was amended in 2022 to include co-treatment of methotrexate to prolong efficacy and increases tolerability in patients with refractory gout. Krystexxa is no longer marketed in the European Union. The EC withdrew the marketing authorization for Krystexxa in 2016 at the request of the marketing authorization holder which notified the EC of its decision not to market the product in the European Union for commercial reasons. We believe that new effective, safe therapies are needed to treat severe gout, chronic refractory and uncontrolled gout, regardless of treatment history.

PRX-119

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

The administration of PRX-119 resulted in a decrease in circulating of DNA levels and significantly enhanced the survival of mice in both a CLP-induced sepsis model and an ARDS model.

Intellectual Property

A key element of our overall strategy is to establish a broad portfolio of patents to protect our proprietary technology, proprietary product and product candidates and their methods of use. As of September 30, 2025, we hold a broad portfolio of 16 patent families consisting of approximately 67 patents in Europe, the United States, Israel and additional countries worldwide, as well as approximately 43 pending patent applications.

Research & Development

We continuously work on the further development of our ProCellEx plant cell expression technology and bioreactor system.

Consistent with our corporate strategy, we are focusing on new, early-stage product candidates that treat indications for which there are high unmet needs in terms of efficacy and safety, including renal diseases. Treatments of interest will address both genetic and non-genetic diseases. We intend to use our ProCellEx platform and PEGylation capabilities, as well as other modalities such as small

molecules and oligonucleotides, to take advantage of highly innovative opportunities. We are also exploring novel platform technologies.

Critical Accounting Policies

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing in this Quarterly Report. There have been no material changes to our critical accounting policies since we filed our Annual Report on Form 10-K for the year ended December 31, 2024.

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

Results of Operations

Three months ended September 30, 2025 compared to the three months ended September 30, 2024

Revenues from Selling Goods

We recorded revenues from selling goods of $17.7 million during the three months ended September 30, 2025, a decrease of $0.1 million, or 1%, compared to revenues of $17.8 million for the three months ended September 30, 2024. The decrease resulted primarily from a decrease of $3.6 million in sales to Chiesi and of $0.6 million in sales to Pfizer, partially offset by an increase of $4.1 million in sales to Fiocruz (Brazil).

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $0.2 million for the three months ended September 30, 2025, an increase of $0.1 million, or 100%, compared to license and R&D services of $0.1 million for the three months ended September 30, 2024. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. Other than potential regulatory milestone payments that may become payable, we expect to generate minimal revenues from license and R&D services now that we have completed the clinical development of Elfabrio.

Cost of Goods Sold

Cost of goods sold was $8.3 million for the three months ended September 30, 2025, a decrease of $0.1 million, or 1%, from cost of goods sold of $8.4 million for the three months ended September 30, 2024. The decrease in cost of goods sold was primarily the result of the decrease in sales to Chiesi and Pfizer partially offset by the increase in sales to Fiocruz (Brazil).

Research and Development Expenses

For the three months ended September 30, 2025, our total research and development expenses were approximately $4.5 million comprised of approximately $2.6 million of salary and related expenses, approximately $0.5 million in subcontractor-related expenses, approximately $0.5 million of materials-related expenses and approximately $0.9 million of other expenses. For the three months ended September 30, 2024, our total research and development expenses were approximately $3.0 million comprised of approximately $1.6 million of salary and related expenses, approximately $0.6 million in subcontractor-related expenses, approximately $0.2 million of materials-related expenses and approximately $0.6 million of other expenses.

Total increase in research and developments expenses for the three months ended September 30, 2025 was $1.5 million, or 50%, compared to research and developments expenses of $3.0 million for the three months ended September 30, 2024. The increase in research and development expenses resulted primarily from preparations for the planned phase 2 clinical trial of PRX-115.

We expect to continue to incur significant, increasing research and development expenses as we enter into a more advanced stage of preclinical and clinical trials for certain of our product candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.9 million for the three months ended September 30, 2025, an increase of $0.3 million, or 12%, compared to $2.6 million for the three months ended September 30, 2024. The increase resulted primarily from an increase of $0.1 million in salary and related expenses and an increase of $0.2 million in selling expenses.

Financial Income (Expenses), Net

Financial income, net was $0.1 million for the three months ended September 30, 2025, compared to financial expenses, net of $0.1 million for the three months ended September 30, 2024. The decrease in financial expenses, net resulted primarily from lower notes interest expenses due to the September 2024 repayment in full of all the outstanding principal and interest payable under the 2024 Notes.

Taxes on Income (Tax Benefit)

We recorded tax benefit of approximately $0.1 million for the three months ended September 30, 2025, compared to tax expenses of approximately $0.6 million for the three months ended September 30, 2024. The tax expenses or benefit resulted primarily from taxes on income mainly derived from GILTI income mainly in respect of Section 174 of the TCJA. Effective in 2022, Section 174 of the TCJA requires all U.S. companies, for tax purposes, to capitalize and subsequently amortize R&D expenses that fall within the scope of Section 174 over five years for research activities conducted in the United States and over 15 years for research activities conducted outside of the United States, rather than deducting such costs in the current year. On July 4, 2025, tax reform legislation was enacted in the United States through the passage of HR1 which includes significant corporate tax changes, including a restoration of the current deductibility for domestic research expenditures beginning in 2025, with transition options for previously capitalized amounts.

Nine months ended September 30, 2025 compared to the nine months ended September 30, 2024

Revenues from Selling Goods

We recorded revenues from selling goods of $43.1 million during the nine months ended September 30, 2025, an increase of $8.3 million, or 24%, compared to revenues of $34.8 million for the nine months ended September 30, 2024. The increase resulted primarily from an increase of $4.5 million in sales to Chiesi and of $4.0 million in sales to Pfizer, partially offset by a decrease of $0.2 million in sales to Fiocruz (Brazil).

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $0.5 million for the nine months ended September 30, 2025, an increase of $0.1 million, or 25%, compared to revenues from license and R&D services of $0.4 million for the nine months ended September 30, 2024. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. Other than potential regulatory milestone payments that may become payable, we expect to generate minimal revenues from license and R&D services now that we have completed the clinical development of Elfabrio.

Cost of Goods Sold

Cost of goods sold was $22.4 million for the nine months ended September 30, 2025, an increase of $2.0 million, or 10%, from cost of goods sold of $20.4 million for the nine months ended September 30, 2024. The increase in cost of goods sold was primarily the result of an increase in sales to Chiesi and Pfizer partially offset by a decrease in sales to Fiocruz (Brazil).

Research and Development Expenses

For the nine months ended September 30, 2025, our total research and development expenses were approximately $13.9 million comprised of approximately $6.5 million of salary and related expenses, approximately $4.3 million in subcontractor-related expenses, approximately $0.9 million of materials-related expenses and approximately $2.2 million of other expenses. For the nine months ended September 30, 2024, our total research and development expenses were approximately $8.8 million comprised of approximately $4.8 million of salary and related expenses, approximately $1.6 million of subcontractor-related expenses, approximately $0.5 million of materials-related expenses and approximately $1.9 million of other expenses.

Total increase in research and developments expenses for the nine months ended September 30, 2025 was $5.1 million, or 58%, compared to research and developments expenses of $8.8 million for the nine months ended September 30, 2024. The increase in research and development expenses resulted primarily from preparations for the planned phase 2 clinical trial of PRX-115.

We expect to continue to incur significant, increasing research and development expenses as we enter into a more advanced stage of preclinical and clinical trials for certain of our product candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $8.2 million for the nine months ended September 30, 2025, a decrease of $1.0 million, or 11%, compared to $9.2 million for the nine months ended September 30, 2024. The decrease resulted primarily from a decrease of $0.7 million in salary and related expenses and a decrease of $0.3 million in selling expenses.

Financial Income (Expenses), Net

Financial income, net was $0.01 million for the nine months ended September 30, 2025, compared to financial income, net of $0.1 million for the nine months ended September 30, 2024. The decrease resulted primarily from exchange rate costs and lower interest income on bank deposits partially offset by lower notes interest expenses due to the September 2024 repayment in full of all the outstanding principal and interest payable under the 2024 Notes.

Taxes on Income (Tax Benefit)

We recorded tax expenses of approximately $0.3 million for the nine months ended September 30, 2025, compared to tax expenses of approximately $0.4 million for the nine months ended September 30, 2024. The tax expenses or benefit resulted primarily from taxes on income mainly derived from GILTI income mainly in respect of Section 174 of the TCJA. Effective in 2022, Section 174 of the TCJA requires all U.S. companies, for tax purposes, to capitalize and subsequently amortize R&D expenses that fall within the scope of Section 174 over five years for research activities conducted in the United States and over 15 years for research activities conducted outside of the United States, rather than deducting such costs in the current year. On July 4, 2025, tax reform legislation was enacted in the United States through the passage of HR1 which includes significant corporate tax changes, including a restoration of the current deductibility for domestic research expenditures beginning in 2025, with transition options for previously capitalized amounts.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and short-term bank deposits. At September 30, 2025, we had $29.4 million in cash and cash equivalents and short-term bank deposits. In September 2024, we satisfied the outstanding principal and accrued interest under the 2024 Notes with a cash payment of approximately $21.2 million which was available primarily from the withdrawal of short-term deposits. We have primarily financed our operations through sales proceeds, equity and debt financings, business collaborations, and grants funding.

During the nine-month period ended September 30, 2025, we sold, in the aggregate, 2,775,215 shares of Common Stock under the Sales Agreement generating gross proceeds equal to approximately $7.0 million. In March 2025, we amended the Sales Agreement to provide for the offer and sale of up to an additional $20.0 million in shares of Common Stock. As of September 30, 2025, approximately $15.7 million in shares of Common Stock remain available to be sold under the Sales Agreement.

We believe that our cash and cash equivalents and short-term bank deposits are sufficient to satisfy our capital needs for at least 12 months from the date this report is issued.

Cash Flows

Net cash used in operations was $14.0 million for the nine months ended September 30, 2025. The net loss for the nine months ended September 30, 2025 of $1.1 million was increased by a $11.8 million increase in accounts receivable-trade and other assets, a $4.0 million decrease in accounts payable and accruals, and was offset by a $1.6 million in share-based compensation and $1.1 million in depreciation. Net cash used in investing activities for the nine months ended September 30, 2025 was $1.3 million and consisted primarily of the purchase of property and equipment. Net cash provided by financing activities for the nine months ended September 30, 2025 was $9.2 million and consisted of $6.8 million proceeds from issuance of Common Stock under the Sales Agreement, net and $2.4 million from the exercise of warrants and options.

Net cash provided by operations was $4.7 million for the nine months ended September 30, 2024. The net loss for the nine months ended September 30, 2024 of $3.6 million was increased by a $0.7 million decrease in accounts payable and accruals and was offset by a $3.1 million decrease in accounts receivable-trade and other assets, $2.6 million in share-based compensation, a $1.8 million decrease in inventories and $1.0 million in depreciation. Net cash provided by investing activities for the nine months ended September 30, 2024 was $19.5 million and consisted primarily of $20.4 million in proceeds from the sale of deposits partially offset by a $0.9 million purchase of property and equipment. Net cash used in financing activities for the nine months ended September 30,

2024 was $20.4 million representing the payment of the outstanding principal and accrued interest under our 2024 Notes which matured in September 2024.

Future Funding Requirements

Since our inception, we have incurred significant research and development expenditures which have not been offset by revenues. We have not generated significant revenues from sales of Elelyso or Elfabrio. We have generated operating losses from our continuing operations since our inception although the revenues generated in the years ended December 31, 2023 and 2024 exceeded our expenditures for the same periods.

As the 2024 Notes were paid in full during the year ended December 31, 2024, we are no longer subject to the financial limitations related to such notes.

As we increase our research and developments efforts with respect to our current and future product candidates, we expect to continue to incur significant expenditures. We cannot anticipate the costs or the timing of the occurrence of such costs. Although we expect the revenues generated from the sales of Elfabrio and Elelyso will increase, such revenues may not be sufficient to fund the expenditures. To the extent we need to obtain additional financing in excess of such anticipated revenues, it may be difficult for us to do so given the volatility of the price of our Common Stock. Our material cash needs for the next 24 months will include, among other expenses, (i) costs of preclinical and clinical trials, (ii) employee salaries, (iii) payments for rent and operation of our manufacturing facilities, (iv) fees to our consultants and legal advisors, patent advisors and fees for service providers in connection with our research and development efforts and (v) tax payments. We believe that the funds currently available to us are sufficient to satisfy our capital needs for at least 12 months from the date this report is issued.

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

- the duration and cost of discovery and preclinical development and laboratory testing and clinical trials for our product candidates;
- Chiesi's progress in commercializing Elfabrio;
- our progress in commercializing BioManguinhos alfataliglicerase in Brazil;
- the timing and outcome of regulatory review of our product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights; and
- the costs associated with any litigation claims.

We expect to finance our future cash needs through sales of Elfabrio and Elelyso, corporate collaborations, licensing or similar arrangements, public or private equity offerings and/or debt financings. We currently do not have any commitments for future external funding, except with respect to the milestone payments that may become payable under the Chiesi Agreements.

Effects of Currency Fluctuations

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services and salaries expenses. For the three and nine months ended September 30, 2025 the currency fluctuations were $0.2 million and $0.8 million, respectively.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2025 and December 31, 2024.

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. Most of our revenues and more than 50% of our expenses and capital expenditures are and were incurred in dollars, and a significant source of our financing has

been provided in U.S. dollars. Since the dollar is the functional currency, monetary items maintained in currencies other than the dollar are remeasured using the rate of exchange in effect at the balance sheet dates and non-monetary items are remeasured at historical exchange rates. Revenue and expense items are remeasured at the average rate of exchange in effect during the period in which they occur. Foreign currency translation gains or losses are recognized in the statement of operations.

Approximately 44% of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A revaluation of 1% of the NIS will affect our loss before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2025	2024	2025	2024	2024
Average rate for period	3.364	3.715	3.519	3.701	3.700
Rate at period-end	3.306	3.710	3.306	3.710	3.647

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.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended September 30, 2025 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, 2024.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

During the quarter ended September 30, 2025, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

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	001-33357	3.1	April 1, 2016	
3.2	Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	July 1, 2016	
3.3	Second Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	October 17, 2018	
3.4	Third Amendment to Certificate of Incorporation of the Company	8-K	001-33357	3.1	December 19, 2019	
3.5	Fourth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.5	August 15, 2022	
3.6	Fifth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.6	August 7, 2023	
3.7	Second Amended and Restated Bylaws of the Company	10-Q	001-33357	3.7	May 9, 2025	
4.1†	Form of Restricted Stock Agreement/Notice	8-K	001-33357	4.1	July 18, 2012	
4.2	Description of Capital Stock	10-K	001-33357	4.7	March 14, 2024	
4.3†	Form of Stock Option Agreement (Executives)	10-Q	001-33357	4.8	August 10, 2020	
4.4	Form of Stock Option Agreement (Standard)	10-Q	001-33357	4.9	August 10, 2020	
10.1††	Amended and Restated Exclusive License and Supply Agreement by and between Pfizer Inc. and Protalix Ltd., dated October 12, 2015					X

31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-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 Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X
32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer	X
32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer	X
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document	X
101.SCH	Inline XBRL Taxonomy Extension Schema Document	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	X
104	COVER PAGE INTERACTIVE DATA FILE (formatted as Inline XBRL and contained in Exhibit 101).	

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

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

SIGNATURES

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

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: November 13, 2025

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

Date: November 13, 2025

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

Exhibit 10.1

Portions of this exhibit have been omitted pursuant to Item 601(b)(10) of Regulation S-K on the basis that they are not material and are the type of information that the Registrant treats as confidential and private. The omitted portions, marked by [***], have been separately filed with the Securities and Exchange Commission.

AMENDED AND RESTATED
EXCLUSIVE LICENSE AND SUPPLY AGREEMENT

by and between

PFIZER INC.

and

PROTALIX LTD.

October 12, 2015

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Appendix 7.2(a) – Protalix Account Information

Appendix 7.2(b) – Pfizer Account Information

Appendix 10.1(t) – Pfizer's Anti-Bribery and Anti-Corruption Principles

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

AMENDED AND RESTATED EXCLUSIVE LICENSE AND SUPPLY AGREEMENT

This Amended and Restated Exclusive License and Supply Agreement (this "Agreement") dated as of October 12, 2015 (the "Second Amendment Effective Date") between Protalix Ltd., a limited liability company incorporated under the laws of Israel with offices located at 2 Snunit Street, Science Park, P.O.B. 455, Carmiel 20100, Israel ("Protalix"), and Pfizer Inc., a Delaware corporation with offices located at 235 East 42nd Street, New York, New York, 10017, U.S.A. ("Pfizer").

WHEREAS, Protalix and Pfizer are parties to that certain Exclusive License and Supply Agreement (the "Original Agreement") dated November 30, 2009, pursuant to which Protalix provided Pfizer with an exclusive license in all countries of the world other than Israel to certain patents, patent applications, technology, know how and scientific and technical information relating to an enzyme replacement therapy for the treatment of Gaucher Disease;

WHEREAS, Protalix and Pfizer amended the Original Agreement pursuant to the Amendment to the Exclusive License and Supply Agreement (the "First Amendment" and, the Original Agreement as amended by the First Amendment, the "Amended Agreement") dated June 18, 2013 (the "Amendment Effective Date") pursuant to which the parties amended the territory and other terms with respect to Brazil; and

WHEREAS, Protalix and Pfizer wish to further amend and also restate in its entirety the Amended Agreement (including, for the avoidance of doubt, the First Amendment) to modify the territory and make such other changes as set forth herein, with the effect that the Original Agreement and First Amendment shall be superseded hereby.

NOW, THEREFORE, in consideration of the mutual covenants and agreements provided herein, Protalix and Pfizer hereby agree that the Amended Agreement is hereby amended and restated in its entirety to read as follows:

SECTION 1. DEFINITIONS

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

1.1 "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 50% of the voting securities or other ownership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity, it being understood and agreed that for purposes of clause (a), neither ownership of voting securities or other ownership interests of an entity nor membership or representation on (if less than half of the members of) an entity's board of directors shall, by themselves, be presumed to constitute the power to direct or cause direction of the management or policies of such entity. With respect to the grant of license rights by Protalix

to Pfizer under Section 3, "Affiliate" shall exclude any Third Party that becomes an Affiliate due to such Third Party's acquisition of Protalix.

1.2 "Allocation Percentage" shall have the meaning assigned to it in Section 5.2(c).

1.3 "Amended Agreement" shall have the meaning assigned to it in the Recitals.

1.4 "Amendment Effective Date" shall have the meaning assigned to it in the Recitals.

1.5 [***]

1.6 "Brazil Activities" shall have the meaning assigned to it in Section 3.6(b).

1.7 "Brazil Uplyso Trademark" means the trademark "UPLYSO™" registered in Brazil, as set forth in Exhibit D, as such Exhibit D may be updated by mutual agreement of the parties within thirty (30) days following the Second Amendment Effective Date.

1.8 "Business Associates" shall have the meaning assigned to it in Appendix 10.1(t).

1.9 "Business Day" means a day other than a Saturday, Sunday, or bank or other public holiday in New York, New York.

1.10 "Capacity Cap" shall have the meaning assigned to it in Section 5.2(c).

1.11 "Capacity Expansion Project" shall have the meaning assigned to it in Section 5.2(b).

1.12 "Change of Control" means any transaction or series of related transactions that would occasion: (a) any share exchange, re-capitalization, business combination, consolidation, merger, or other transaction or series of transactions resulting in the exchange of the outstanding shares of a party, unless the stockholders of a party that exist immediately prior to the closing date of such transaction (or series of related transactions) hold, after the closing date, more than fifty percent (50%) of the voting securities or other similar interest of the surviving entity in such transaction computed on a fully diluted basis; (b) a sale, lease, or other transfer of all or substantially all of the stock or assets of a party; (c) any tender offer or exchange offer for fifty percent (50%) or more of the outstanding voting securities or other similar interest of a party or the filing of a registration statement under the United States Securities Act of 1933, as amended, in connection therewith; or (d) any Person or group acting in concert having acquired beneficial ownership or the right to acquire beneficial ownership of fifty percent (50%) or more of the outstanding voting securities or similar interest of a party.

1.13 "Commercialization" means, with respect to a product or compound (including any Compound, Licensed Product, Drug Substance or Competing Product), any activities directed to and including marketing, promoting, distributing, offering for sale and selling such product or compound, importing such product or compound (to the extent applicable) and

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

conducting [***]. When used as a verb, "Commercialize" means to engage in Commercialization.

1.14 "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 Development or Commercialization of the Licensed Product in the Territory by Pfizer, such efforts shall be similar to those efforts and resources consistent with the usual practice of Pfizer in pursuing the Development or 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 Pfizer'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.

1.15 "Competing Product" means [***]

1.16 "Compliance Questionnaire" shall have the meaning assigned to it in Section 10.1(s).

1.17 "Compound" means (a) prGCD and (b) any analogs, derivatives and variants thereof.

1.18 "Confidential Information" means the Protalix Confidential Information or the Pfizer Confidential Information, as applicable.

1.19 "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 Second Amendment Effective Date or (b) any law or governmental regulation applicable to such license or sublicense.

1.20 "Country" means any generally recognized sovereign entity.

1.21 "Court" shall have the meaning assigned to it in Section 17.2.

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

1.22 "Development" or "Develop" means conducting pre-clinical studies and clinical trials, collecting, validating and analyzing pre-clinical and clinical trial data, preparing and submitting regulatory filings, obtaining Regulatory Approvals, and regulatory affairs related to the foregoing. When used as a verb, "Develop" means to engage in Development. For clarity, Development does not include Phase 4 Trials or any of the foregoing in connection therewith.

1.23 "Divestiture" shall have the meaning assigned to it in Section 18.7.

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

1.25 "Early Access Program" means any program to provide patients with the Licensed Product prior to Regulatory Approval and prior to Launch in any Country in the Territory. Early Access Programs include treatment INDs / protocols in the United States, named patient programs in the EU and compassionate use programs in other Countries in the Territory.

1.26 "Effective Date" means the date of the Original Agreement.

1.27 "EMEA" means the European Agency for the Evaluation of Medicinal Products or any successor agency thereto.

1.28 "Environmental Laws" means all applicable Laws relating to (a) safety (including occupational health and safety); conservation, preservation or protection of human health, drinking water, natural resources, biota and the environment; (b) the generation, use, storage, handling, treatment, transportation or disposal of Hazardous Materials or Waste, (c) Releases and threatened Releases of Hazardous Materials, or (d) chemical classification and labeling.

1.29 "Environmental Permits" shall have the meaning assigned to it in Section 10.3(a)(ii).

1.30 "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.

1.31 "Expansion Costs" shall have the meaning assigned to in Section 5.2(b).

1.32 "Facility" means, as applicable, a party's Manufacturing facility and such other facilities used by such party (or its Affiliates) in the Manufacture or storage of (a) Drug Substance, (b) Licensed Product or (c) materials utilized in the Manufacture of Drug Substance or Licensed Product.

1.33 "Failure to Supply" shall have the meaning assigned to it in Section 5.21(a).

1.34 "FCPA" shall have the meaning assigned to it in Appendix 10.1(t).

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

1.36 "FDCA" means the U.S. Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder.

1.37 "Field" means enzyme replacement therapy for the treatment of Gaucher Disease.

1.38 "Fill/Finish" means (a) formulating the Licensed Product using Drug Substance and other excipients, (b) filling the Licensed Product into vials, (c) lyophilization of the Drug Substance for incorporation into the Licensed Product, and (d) testing, including ongoing stability testing, and release of the Licensed Product. For the avoidance of doubt, Fill/Finish shall not include any activities included in the definition of Labeling and Packaging.

1.39 "Fiocruz" means Fundação Oswaldo Cruz, an agency of the Brazilian Ministry of Health organized under the Laws of Brazil.

1.40 "First Amendment" shall have the meaning assigned to it in the Recitals.

1.41 "Force Majeure Event" shall have the meaning assigned to it in Section 18.1.

1.42 "Forecast" shall have the meaning assigned to it in Section 5.6(a).

1.43 "FTE Rate" means [***] per full time equivalent person engaged in scientific, regulatory, process development, manufacturing or other similar work, consisting of [***] hours per year of such qualified work.

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

1.45 "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, 211, 601 and 610, (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.

1.46 "Government Official" shall have the meaning assigned to it in Section 10.1(r).

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

1.48 "Hazardous Materials" means any and all materials (including substances, chemicals compounds, mixtures, products, byproducts, biologic agents, living or genetically modified materials, wastes, pollutants and contaminants), that are (a) (i) listed, classified,

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

characterized or regulated pursuant to Environmental Laws; (ii) identified or classified as "hazardous", "dangerous", "toxic", "pollutant", "contaminant", "waste", "irritant", "corrosive", "flammable", "radioactive", "reactive", "carcinogenic", "mutagenic", "bioaccumulative", or "persistent" in the environment; or (iii) in quantity or concentration capable of causing harm or injury to human health, natural resources or the environment, if Released or resulting in human exposure; or (b) petroleum products and their derivatives, asbestos-containing material, lead-based paint, polychlorinated biphenyls, urea formaldehyde, or viral, bacterial or fungal material.

1.49 "Improvement Notice" shall have the meaning assigned to in Section 3.5.

1.50 "Increased Capacity Cap" shall have the meaning assigned to it in Section 5.2(b).

1.51 "IND" means an investigational new drug application filed with the FDA in accordance with the FDCA 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 agency such as the European Union) for the purpose of commencing clinical development of a drug product in such jurisdiction.

1.52 "Indemnified Party" shall have the meaning assigned to it in Section 15.3(a).

1.53 "Indemnifying Party" shall have the meaning assigned to it in Section 15.3(a).

1.54 "Initial Forecast" shall have the meaning assigned to it in Section 5.6(a).

1.55 "Inventories" shall have the meaning assigned to it in Section 4.2(c).

1.56 "Israel Grant" shall have the meaning assigned to it in Section 10.1(i).

1.57 "IU" shall have the meaning assigned to it in Section 5.7(a).

1.58 "Labeling and Packaging" means the final product labeling and packaging of the Licensed Product (whether in commercial or clinical packaging presentation), including materials to be inserted such as patient inserts, patient medication guides, professional inserts and any other written, printed or graphic materials accompanying the Licensed Product.

1.59 "Launch" means the first shipment of a Licensed Product in commercial quantities for commercial sale by Pfizer, its Affiliates or its Sublicensees to a Third Party in a Country in the Territory after receipt by Pfizer of the first Regulatory Approval (and, in any Country in which Price Approval is necessary or relevant for a majority of the population to obtain access to drug products, Price Approval) for such Licensed Product in such Country.

1.60 "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.

1.61 "Licensed Product" means any finished dosage form of a drug product that contains Drug Substance (excluding any Oral Formulation) and either: (a) the manufacture, sale,

offer for sale, importation, or use of such drug product (i) would, absent the license granted by Protalix to Pfizer herein, infringe at least one Valid Claim of a Protalix Patent Right, or (ii) embodies, incorporates or uses Protalix Technology; or (b) such drug product is supplied by Protalix to Pfizer under this Agreement (or is manufactured using Drug Substance supplied by Protalix to Pfizer under this Agreement) or is manufactured by Pfizer or a Third Party (or is manufactured using Drug Substance manufactured by Pfizer or a Third Party).

1.62 "Long Range Forecast" shall have the meaning assigned to it in Section 5.6(b).

1.63 "Losses" shall have the meaning assigned to it in Section 15.2.

1.64 "Manufacture" or "Manufacturing" means all activities related to the manufacturing of the Drug Substance or Licensed Product, and/or any ingredient thereof, including manufacturing for clinical use or commercial sale, in-process and finished product testing, Fill/Finish, Labeling and Packaging, release of product, quality assurance activities related to manufacturing and release of product and ongoing stability tests and regulatory activities related to any of the foregoing.

1.65 "Manufacturing Certificate of Analysis" shall have the meaning assigned to it in Section 5.10(a)(i).

1.66 "Manufacturing Transition Plan" shall have the meaning assigned to it in Section 5.23.

1.67 "Minimum Delivery Requirements" shall have the meaning assigned to it in Section 5.21(a).

1.68 "Minimum Shelf Life" shall have the meaning assigned to it in Section 5.8(b).

1.69 "NDA" means a New Drug Application filed with the FDA in accordance with the FDCA 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 agency such as the European Union) for the purpose of obtaining approval to market and sell a drug product in such jurisdiction.

1.70 "Notice of Non-Conformance" shall have the meaning assigned to it in Section 5.10(a)(ii).

1.71 "Oral Formulation" means an oral formulation of a drug product for the treatment of Gaucher Disease which contains any Compound as the active pharmaceutical ingredient.

1.72 "Original Agreement" shall have the meaning assigned to it in the Recitals.

1.73 "Outside of the Scope Product" shall have the meaning assigned to it in Section 8.2.

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

1.75 "Patent Challenge" has the meaning assigned to it in Section 3.7(a).

1.76 "Patent Rights" means Patents and Patent Applications.

1.77 "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.

1.78 "Persistent Failure to Supply" shall have the meaning assigned to it in Section 5.21(b).

1.79 "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.

1.80 "Pfizer Confidential Information" means all information relating to the Compound or Licensed Product, as well as any other information regarding the business and operations of Pfizer, that is or has been disclosed (whether orally or in writing) by Pfizer to Protalix or its Affiliates to the extent that such information is not: (a) as of the date of disclosure known to Protalix or its Affiliates; or (b) disclosed in published literature, or otherwise generally known to the public through no breach by or Protalix; of this Agreement or (c) obtained by Protalix or its Affiliates from a Third Party free from any obligation of confidentiality to Pfizer; or (d) independently developed by Protalix or its Affiliates without use of the Pfizer Confidential Information; or (e) in the good faith judgment of Protalix, after consultation with legal counsel, is required to be disclosed under Law; provided that, in the case of (e), Protalix provides Pfizer prior notice (to the extent practicable) of such disclosure and agrees to cooperate, at the request and sole expense of Pfizer, with Pfizer's efforts to preserve the confidentiality of such information.

1.81 "Pfizer Improvements" has the meaning assigned to it in Section 3.6(d).

1.82 "Pfizer Payment" has the meaning assigned to it in Section 6.1.

1.83 "Phase 4 Trial" means a clinical trial for the Licensed Product that is initiated in a Country after receipt of Regulatory Approval for the Licensed Product in such Country and is principally intended to support the marketing and Commercialization of the Licensed Product, including investigator initiated trials and clinical experience trials. "prGCD" means a plant cell expressed recombinant human Glucocerebrosidase enzyme having the sequence set forth in Exhibit A to this Agreement.

1.84 "Presentation" means [***].

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

1.85 "Price" means the price Pfizer pays to Protalix per IU of Drug Substance manufactured for and shipped to Pfizer.

1.86 "Price Approval" means, in any Country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, drug products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be).

1.87 "Product Mark" shall have the meaning assigned to in Section 4.4(b).

1.88 "Product Specifications" means those Manufacturing, performance, quality - control release, and Fill/Finish specifications for Drug Substance 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.

1.89 "Proposed Transaction" shall have the meaning assigned to it in Section 11.7.

1.90 "Protalix Confidential Information" [***]

1.91 "Protalix Improvement" means any necessary or useful improvement, change, or modification to the Drug Substance, Licensed Product or Protalix Technology which may be developed, created, or acquired by Protalix after the Effective Date and before termination of this Agreement, including new or improved methods of Manufacturing, means of delivery (other than an Oral Formulation), dosage, formulation (other than an Oral Formulation), and analysis. To the extent an improvement, change or modification to prGCD also constitutes an analog, derivative or variant of prGCD, such improvement, change or modification shall be deemed to be a Compound and not a Protalix Improvement.

1.92 "Protalix Patent Rights" [***]

1.93 "Protalix Payment" has the meaning assigned to it in Section 6.2.

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

1.95 "Protalix Technology" means any Technology owned or otherwise Controlled by Protalix or any of its Affiliates as of the Second Amendment 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.

1.96 "Protalix Withholding Tax Action" has the meaning assigned to in Section 7.3(c)(iii).

1.97 "Purchase Order" shall have the meaning assigned to it in Section 5.6(a).

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

1.98 "Quality Agreement" means the Quality Agreement entered into between Protalix and Pfizer, dated January 4, 2011, with respect to the Drug Substance being Manufactured by Protalix [***] in the Territory.

1.99 "Redacted Agreement" shall have the meaning assigned to it in Section 9.5.

1.100 "Regulatory Approval" means any and all approvals, with respect to any Country, or authorizations (other than Price Approvals) of a Regulatory Authority, that are necessary for the commercial Manufacture, distribution, use, marketing or sale of a drug product in such Country.

1.101 "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.

1.102 "Regulatory Exclusivity" means any rights or protections which are recognized, afforded or granted by a Regulatory Authority in any Country or region of the Territory, 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 party other than Pfizer, its Affiliates or Sublicensees 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 party, other than Pfizer, its Affiliates or Sublicensees, 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. Regulatory Exclusivity shall include rights conferred in the United States pursuant to the Hatch-Waxman Act or the FDA Modernization Act of 1997 or in the European Union/European Economic Area pursuant to Section 10.1 of Directive 2001/EC/83 or section 14.11 of Regulation (EC) No. 726/2004.

1.103 "Release" means any release, spill, emission, leaking, pumping, injection, deposit, disposal, discharge, dispersal, leaching or migration into the indoor or outdoor environment, including the uncontrolled presence or the movement of Hazardous Materials through the ambient air, soil, subsurface water, groundwater, wetlands, lands or subsurface strata.

1.104 "Released Obligations" has the meaning assigned to it in Section 6.5.

1.105 "Resulting Companies" shall have the meaning assigned to it in Section 18.7(a).

1.106 "Second Amendment Effective Date" shall have the meaning assigned to it in the Recitals.

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

1.107 "Sublicense" means the grant by Pfizer of a sublicense under, or an agreement of Pfizer not to assert, any of the rights licensed by Protalix to Pfizer pursuant to Section 3.1.

1.108 "Sublicensee" means a Third Party to whom Pfizer has granted a Sublicense.

1.109 "Supply Term" shall have the meaning assigned to it in Section 5.5**.**

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

1.111 "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 any Patent Rights.

1.112 "Technology Transfer Agreement" means the Technology Transfer and Supply Agreement between Protalix and Fiocruz, dated June 18, 2013.

1.113 "Term" shall have the meaning assigned to it in Section 13.

1.114 "Territory" means the entire world, excluding Brazil.

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

1.116 "Third Party Claim" shall have the meaning assigned to it in Section 15.3.

1.117 "Third Party License" means each license agreement between Protalix and a Third Party set forth on Exhibit C pursuant to which or from which Protalix licenses Protalix Patent Rights or Protalix Technology.

1.118 "Transition Manager" shall have the meaning assigned to it in Section 4.7(a).

1.119 "Transition Period" shall have the meaning assigned to it in Section 4.7(a).

1.120 "Transition Plan" shall have the meaning assigned to it in Section 4.7(b).

1.121 "Transition Team" shall have the meaning assigned to it in Section 4.7(a).

1.122 "Unmatured Note" shall have the meaning assigned to it in Section 5.21(b)(i).

1.123 "Uplyso Trademarks" means the trademark "UPLYSO™" in certain countries in the world.

1.124 "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 five (5) 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).

1.125 [***] means [***].

1.126 [***] License Agreement" means that License Agreement by and between Protalix and [***]effective as of [***], as amended from time to time.

1.127 "Waste" means all wastes which arise from the Manufacture, handling or storage of Drug Substance hereunder, or which is otherwise produced through the implementation of this Agreement, including Hazardous Materials.

1.128 "Work Plan" shall have the meaning assigned to it in Section 5.2(b).

1.129 "[***]

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. [INTENTIONALLY OMITTED]

SECTION 3. LICENSE

3.1 Exclusive License. Subject to the terms of this Agreement, including Section 3.2, Protalix hereby grants to Pfizer and Pfizer hereby accepts an exclusive (even as to Protalix and its Affiliates, except as set forth in Section 3.2), irrevocable, perpetual, fully-paid (upon Pfizer's payment of the Pfizer Payment pursuant to Section 6.1 of the Agreement), royalty-free license in the Territory and within the Field, including the right to Sublicense (subject to Section 3.4):

(a) under the Protalix Patent Rights to (i) use, sell, offer for sale, supply, cause to be supplied, and import the Licensed Product, (ii) conduct the Fill/Finish activities and Labeling and Packaging activities, (iii) engage in Development activities with respect to the Licensed Product, and (iv) make and have made the Drug Substance solely for incorporation in the Licensed Product; and

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

(b) to use Protalix Technology and Protalix Confidential Information in connection with (i) the conduct of the Fill/Finish activities and Labeling and Packaging activities, (ii) preparing and submitting regulatory filings and communicating with Regulatory Authorities with respect to the Licensed Product, (iii) the use, sale, offer for sale, supply and importation of the Licensed Product, (iv) Development activities with respect to the Licensed Product, and (v) making and having made the Drug Substance solely for incorporation in the Licensed Product.

3.2 Other License Provisions.

(a) The licenses granted to Pfizer pursuant to Section 3.1 shall be co-exclusive with Protalix only to the extent it is necessary for Protalix to perform its obligations under this Agreement. During the Term, and without limiting the scope of the licenses granted to Pfizer pursuant to Section 3.1, neither Protalix nor any of its Affiliates shall (i) directly or indirectly, alone or in collaboration with any Third Party, Commercialize the Compound (other than the Oral Formulation), a drug product containing the [***]. The parties expressly acknowledge and agree that the exclusivity grant in favor of Pfizer in Section 3.1 shall not be construed as limiting Protalix's right to Develop, Manufacture or Commercialize [***]. Notwithstanding anything to the contrary herein, Protalix may conduct or have conducted Manufacturing activities and engage in or have engaged in Development activities in Israel at any time in connection with its sale, offer for sale, supply or importation of the Licensed Product outside the Territory; provided however, that Protalix shall not be permitted to conduct clinical studies of the [***] within Israel without the prior written consent of Pfizer.

(b) For purposes of clarity, and without limiting the licenses granted under Section 3.1, Pfizer acknowledges that in the event Protalix does not have exclusive rights to Protalix Patent Rights licensed by Protalix from Third Parties [***] vis à vis the Third Party licensor, Pfizer's rights to such Protalix Patent Rights under the sublicenses granted under Section 3.1 would not be exclusive vis à vis the Third Party licensor.

3.3 [***]

3.4 Sublicensing and Subcontracting.

(a) Pfizer may grant Sublicenses subject to the terms and conditions set forth in this Section 3.4. Any Sublicense obligations required by the Third Party License to be included in a sublicense shall be deemed to be included in this Agreement as obligations of Pfizer.

(b) Each Sublicense granted by Pfizer pursuant to Section 3.4(a) shall be subject and subordinate to the terms and conditions of this Agreement and shall contain terms and conditions consistent with those in this Agreement, and shall not in any way diminish, reduce or eliminate any of Pfizer's obligations under this Agreement. Without limiting the foregoing, each Sublicense agreement with Sublicensees shall contain the following provisions: (i) a requirement that such Sublicensee comply with the confidentiality and non-use provisions

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

of Section 9 with respect to both parties' Confidential Information, (ii) a requirement to comply with all other applicable terms of this Agreement, and (iii) a provision prohibiting such Sublicensee from further sublicensing unless such further sublicense complies with the terms of this Section 3.4.

(c) Right to Subcontract. Each party may, subject to Section 9 and Section 3.4(d), subcontract its 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.

(d) Liability for Affiliates, Sublicensees and Subcontractors. Each party shall ensure that each of its Affiliates, sublicensees and subcontractors accepts and complies with all of the applicable terms and conditions of this Agreement as if such Affiliates or sublicensees or subcontractors were parties to this Agreement and each party shall remain fully responsible for its Affiliates' and sublicensees' and subcontractors' performance under this Agreement.

3.5 Improvements.

(a) During the Term, Protalix shall give written notice (an "Improvement Notice") to Pfizer within thirty (30) days of any actual or constructive reduction to practice of any Protalix Improvement. The Improvement Notice shall set forth the nature and details of the Protalix Improvement and any data obtained or generated by Protalix. Where such Protalix Improvements are to an invention, Protalix shall state in the Improvement Notice whether it intends to prepare and file patent applications related thereto. For the avoidance of doubt, the Improvement Notice and its contents shall be deemed Protalix Confidential Information and subject to the confidentiality provisions set forth in Section 9 hereof.

(b) Each Protalix Improvement shall be deemed to be included within the Protalix Technology licensed to Pfizer pursuant to Section 3.1 of this Agreement, without the payment of any additional fees, including milestones or royalties. Any Patent Application directed to a Protalix Improvement shall be considered to be a Protalix Patent Right licensed pursuant to Section 3.1 of this Agreement, without the payment of any additional fees, including milestones or royalties.

3.6. No Implied License; Brazil Activities.

(a) Except for the licenses and other rights granted to Pfizer herein, all right, title and interest in and to the Protalix Patent Rights, Protalix Technology, Protalix Confidential Information and Protalix Improvements shall remain solely with Protalix and its Third Party licensors, as applicable. Except as expressly provided in this Section 3 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.

(b) Notwithstanding anything to the contrary in this Agreement, for the avoidance of doubt, Protalix shall have the (i) sole authority and exclusive right to determine all operating plans and strategies for the Drug Substance and Licensed Product outside the Territory and the exclusive right to research, Develop or Commercialize the Drug Substance or Licensed Product outside the Territory and to Manufacture (including Fill/Finish) the Drug Substance or

Licensed Product for sale outside the Territory, and (ii) right to enter into, and perform any of its obligations under, any agreements (including the Technology Transfer Agreement), including sublicenses, relating to Protalix's rights in clause (i) of this sentence (collectively, the "Brazil Activities"), without obtaining any additional consents from Pfizer with respect thereto or having Pfizer participate therein. For the avoidance of doubt, as used in this Section 3.6(b), the term "Commercialize" includes the activities referred to in Section 1.13 with respect to both Drug Substance and Licensed Product. Without limiting the foregoing, Protalix shall have the right to engage Third Parties to perform Fill/Finish activities for, and/or supply Licensed Product to, Protalix for sale of such Licensed Product outside the Territory.

(c) Pfizer acknowledges and agrees that Protalix is permitted to sublicense to Fiocruz (or any other sublicensee of Protalix in Brazil) the Brazil Uplyso Trademark and any other Product Marks required by applicable Laws to be included on the labeling and packaging of the finished packaged product for use in the Brazil Activities as they exist on the labeling and packaging of finished packaged product at the time such finished packaged product is supplied to Fiocruz (or such sublicensee), and subject to the quality control provisions set forth in the Technology Transfer Agreement (or equivalent provisions in another agreement with the applicable sublicensee), which shall be at least as protective as those set forth in Section 4.4(d). For the avoidance of doubt, the rights granted pursuant to this Section 3.6(c) do not include grants to use the name or trade name of Pfizer (other than the right to sublicense such right to Fiocruz (or any other sublicensee of Protalix in Brazil) to the extent such right is granted to Protalix pursuant to Section 4.5 or required to be made pursuant to Section 4.4(d)(iv)(B)). Any such right to use such name or trade name shall be governed by Section 4.5.

(d) Pfizer acknowledges and agrees that Protalix is permitted to sublicense to Fiocruz any drug product manufacturing-related enhancements that are specifically directed to, or new presentations of, the Licensed Product developed or otherwise owned by Pfizer or its Affiliates ("Pfizer Improvements"), pursuant to the Technology Transfer Agreement (or another agreement with the applicable sublicensee); provided that the Pfizer Improvements are used solely for the Licensed Product by Protalix and Fiocruz (or the applicable sublicensee). Pfizer agrees to consider in good faith any reasonable requests for technical support to transfer technical manufacturing information relating solely to the Pfizer Improvement in connection with such sublicense. Such requests for technical support shall be limited to [***] person hours and should additional technical support be required, Protalix shall provide to Pfizer a written request for such additional technical support. Protalix shall reimburse Pfizer for all actual Pfizer costs associated with such technical support, including out-of pocket expenses and documented employee time at the FTE Rate. For the avoidance of doubt, Pfizer shall be under no obligations to provide any technical support pursuant to this Section 3.6(d).

3.7. [***]

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

SECTION 4. REGULATORY APPROVALS AND MARKETING

4.1 Regulatory Affairs.

(a) Regulatory Affairs in the Territory other than Israel.

(i) Copies of Regulatory Filings. The parties acknowledge that Protalix has provided to Pfizer complete copies of all regulatory filings in the Territory (other than Israel) relating to the Licensed Product, including INDs, filings with the FDA or other Regulatory Authorities, supplements or amendments thereto, all written correspondence with the FDA or other Regulatory Authorities regarding such regulatory filings, and all existing written minutes of meetings and memoranda of conversations between Protalix (including, to the extent practicable, Protalix's investigators) and the FDA or other Regulatory Authorities in Protalix's possession (or in the possession of any of Protalix's agents and subcontractors, such as contract research organizations used by Protalix), to the extent Protalix had the right to access and provide to Pfizer such materials.

(ii) Transfer of Regulatory Filings. The parties acknowledge that Protalix assigned and transferred to Pfizer (i) Protalix's entire right, title and interest in and to the Regulatory Approvals for the Licensed Product in the Field in the Territory (other than Israel) and (ii) Protalix's entire right, title and interest in and to any other regulatory filings in the Territory (other than Israel) with respect to the Drug Substance as incorporated into the Licensed Product (and for the avoidance of doubt, excluding any such regulatory filings with respect to the Drug Substance as a part of any Oral Formulation), or the Licensed Product, and any related data.

(iii) Regulatory Filings. During the Term, and with respect to Israel, following the transfer of ownership of regulatory filings relating to the Drug Substance as incorporated into the Licensed Product (and for the avoidance of doubt, excluding any regulatory filings with respect to the Drug Substance as part of any Oral Formulation), or the Licensed Product in Israel, all regulatory filings with the FDA or other Regulatory Authorities pertaining to the Drug Substance as incorporated into the Licensed Product (and for the avoidance of doubt, excluding any such regulatory filings with respect to the Drug Substance as part of any Oral Formulation), or Licensed Product in the Territory shall be made in the name of Pfizer or its Affiliates in accordance with Section 4.1(g).

(b) Regulatory Affairs in Israel.

(i) Transfer of Regulatory Filings. Within the timeframe set forth by the Transition Team and to the extent permitted by applicable Law, (A) Protalix shall assign and transfer to Pfizer, Protalix's entire right, title and interest in and to all regulatory filings and Regulatory Approvals in Israel with respect to the Drug Substance or Licensed Product in the Field (and for the avoidance of doubt, excluding any such regulatory filings or Regulatory Approvals with respect to the Drug Substance as a part of any Oral Formulation), and any related data, pursuant to instruments to such effect in

form and substance reasonably satisfactory to Pfizer, and shall perform all other actions reasonably requested by Pfizer to effect and confirm such assignment and transfer.

(ii) Copies of Regulatory Filings. Protalix shall provide to Pfizer, at Pfizer's expense, complete copies of any regulatory filings in Israel relating to the Licensed Product, including INDs, NDAs, filings with the Regulatory Authorities, supplements or amendments thereto, all written correspondence with Regulatory Authorities regarding such regulatory filings, and all existing written minutes of meetings and memoranda of conversations between Protalix (including, to the extent practicable, Protalix's investigators) and Regulatory Authorities in Protalix's possession (or in the possession of any of Protalix's agents and subcontractors, such as contract research organizations used by Protalix), to the extent Protalix has the right to access and provide to Pfizer such materials. To the extent available, Protalix shall provide such copies to Pfizer in electronic form.

(c) Regulatory Affairs in Brazil.

(i) Transfer of Regulatory Filings. Within the timeframe set forth by the Transition Team and to the extent permitted by applicable Laws, Pfizer shall assign and transfer to Protalix Pfizer's entire right, title and interest in and to all regulatory filings and Regulatory Approvals in Brazil with respect to the Drug Substance or Licensed Product, and any related data, pursuant to instruments to such effect in form and substance reasonably satisfactory to Protalix, and shall perform all other actions reasonably requested by Protalix to effect and confirm such assignment and transfer.

(ii) Copies of Regulatory Filings. To the extent not already provided by Pfizer, Pfizer shall provide to Protalix, at Protalix's expense, complete copies of any regulatory filings in Brazil relating to the Licensed Product, including INDs, NDAs, filings with the Regulatory Authorities, supplements or amendments thereto, all written correspondence with Regulatory Authorities regarding such regulatory filings, and all existing written minutes of meetings and memoranda of conversations between Pfizer (including, to the extent practicable, Pfizer's investigators) and Regulatory Authorities in Pfizer's possession (or in the possession of any of Pfizer's agents and subcontractors, such as contract research organizations used by Pfizer), to the extent Pfizer has the right to access and provide to Protalix such materials. To the extent available, Pfizer shall provide such copies to Protalix in electronic form.

(d) Cooperation. The parties shall cooperate through the Transition Team to ensure that [***]

(e) Rights of Reference and Access to Data.

(i) [***]

(ii) [***]

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

(iii) [***]

(iv) As the manufacturer and supplier of Drug Substance, Protalix shall provide to Pfizer original copies of any Certificate of Pharmaceutical Product ("CPP") issued to Protalix as necessary to support Pfizer's regulatory filings for the Licensed Product in the Field in the Territory. Protalix shall use Commercially Reasonable Efforts to apply for and obtain such CPP.

(f) Assignment of Contracts. Upon Pfizer's reasonable request and to the extent legally permissible, Protalix shall assign to Pfizer any contract Protalix has entered into with a Third Party that solely relates to the Development of the Licensed Product in the Territory, to the extent Pfizer requests such contract to be assigned and such contract is assignable. Protalix shall provide copies all such contracts to Pfizer's Transition Manager.

(g) Responsibility.

(i) Pfizer shall have the sole authority and exclusive right to determine all regulatory plans and strategies for the Licensed Product in the Field in the Territory. Without limiting the foregoing, subject to Section 4.1(b)(i), Pfizer (or, in any Country in the Territory, one or more of its Affiliates or Sublicensees) will own and be responsible for preparing, seeking, submitting and maintaining all regulatory filings and Regulatory Approvals for the Licensed Product in Field in the Territory, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval. Protalix shall provide (A) such assistance as Pfizer or its Affiliates or Sublicensees reasonably requires to obtain and maintain Regulatory Approvals for the Licensed Product in the Field in the Territory, (B) provide Pfizer with all reasonable assistance and cooperation to take all actions reasonably requested by Pfizer that are necessary to enable Pfizer to comply with any Law applicable to the Licensed Product and (C) provide reasonable assistance to enable Pfizer to obtain or maintain Regulatory Approvals for the Licensed Product in the Field in any Country in the Territory, including by providing CMC, facility, bioanalytical and clinical information and data that Pfizer is required to provide to Regulatory Authorities (to the extent such data is in Protalix's possession and Control). Pfizer or its Affiliates or Sublicensees shall have the sole right to apply for and secure exclusivity rights that may be available under the Law of Countries in the Territory, including any Regulatory Exclusivity. Protalix shall use Commercially Reasonable Efforts to cooperate with Pfizer and its Affiliates and Sublicensees, and to take such reasonable actions to assist Pfizer and its Affiliates and Sublicensees, in obtaining such exclusivity rights in each Country, as Pfizer may reasonably request from time to time. Such requested cooperation and assistance referred to in this Section 4.1(g)(i) (including as referenced in the foregoing sentence and the foregoing subclauses (A), (B) and (C)) shall be provided at [***]

(ii) Once Protalix or its designee Fiocruz (or another applicable sublicensee) has successfully received Regulatory Approval for the Licensed Product in Brazil, Protalix shall have the sole authority and exclusive right to determine all

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

regulatory plans and strategies for the Licensed Product in Brazil. Subject to the foregoing, Protalix or its designee Fiocruz (or another applicable sublicensee) shall have the sole authority and exclusive right to determine all regulatory plans and strategies for the Licensed Product outside the Territory, including the right to file a marketing authorization application in Brazil. Without limiting the foregoing, subject to Section 4.1(c)(i), Protalix (or Fiocruz or such other sublicensee) will own and be responsible for preparing, seeking, submitting and maintaining its marketing application and all regulatory filings and Regulatory Approvals for the Licensed Product outside the Territory, including preparing all reports necessary as part of a regulatory filing or Regulatory Approval. Pfizer shall provide such assistance as Protalix reasonably requires to obtain Regulatory Approvals for the Presentation of the Licensed Product Commercialized as of the Second Amendment Effective Date in Brazil. Until Protalix or its designee Fiocruz (or such other applicable sublicensee) has successfully received Regulatory Approval for the Licensed Product in Brazil (and the corresponding marketing authorization held by Pfizer or its Affiliate in Brazil has been cancelled), Protalix and its designee Fiocruz (or such other applicable sublicensee) shall have express and irrevocable authorization and approval for Protalix and its designee Fiocruz (or such other applicable sublicensee) to import the Licensed Product and Drug Substance into Brazil under Pfizer's or its Affiliates' Regulatory Approvals with Regulatory Authorities in Brazil, as allowed under applicable Law, which express authorization and approval is set forth in writing on Exhibit E. Pfizer or its relevant Affiliate shall issue one or more of such authorizations as reasonably required by Protalix or its designee Fiocruz (or such other applicable sublicensee). Protalix, Fiocruz, or such other sublicensee shall have the sole right to apply for and secure exclusivity rights that may be available in Brazil, including any Regulatory Exclusivity. Pfizer shall use Commercially Reasonable Efforts to cooperate with Protalix, Fiocruz or such other sublicensee and to take such reasonable actions to assist Protalix, Fiocruz or such other sublicensee in obtaining such exclusivity rights in Brazil, as Protalix may reasonably request from time to time. Such requested cooperation and assistance shall be provided [***]

(h) Pharmacovigilance. After the Second Amendment Effective Date and prior to[***], the safety units of each of the parties shall meet and agree upon an amendment to the written pharmacovigilance agreement that defines Pfizer's pharmacovigilance responsibilities for the Licensed Product in the Territory and Protalix's pharmacovigilance responsibilities for the Licensed Product outside 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.

(i) Communications with Regulatory Authorities in the Territory. For so long as [***]:

(i) Protalix shall provide Pfizer notice of all meetings, conferences, and discussions (including meeting of experts convened by any Regulatory Authority in Israel concerning any topic relevant to the Licensed Product) scheduled with any Regulatory Authority in Israel concerning any regulatory matters relating to the

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

Licensed Product promptly after the scheduling of such meeting, conference, or discussion (to the extent Protalix is made aware of them in advance). Pfizer or its designee (or such other applicable sublicensee) shall be entitled to have one or more representatives present at all such meetings unless prohibited by applicable Law or unless reasonably impracticable under the circumstances. Pfizer or its designee (or such other applicable sublicensee) and Protalix shall use all reasonable efforts to agree in advance on the scheduling of such meetings, conferences and discussions and on the objectives to be accomplished at such meetings, conferences and discussions and the agenda for the meetings, conferences and discussions with such Regulatory Authority; provided that [***];

(ii) Protalix shall provide Pfizer or its designee (or such other applicable sublicensee) with copies, which copies may be in draft form, of all material submissions to any Regulatory Authority in Israel relating to the Licensed Product, to be provided sufficiently in advance of such planned submission to such Regulatory Authority in order to allow Pfizer or its designee (or such other applicable sublicensee) to provide comments regarding such submission, which comments shall be considered by Protalix in good faith with respect to such submission; provided that [***];

(iii) Protalix shall provide to Pfizer, as soon as reasonably practicable but in no event more than three (3) Business Days after its receipt, copies of any material documents or other material correspondence received from any Regulatory Authority pertaining to the Licensed Product; and

(iv) Protalix shall reasonably cooperate with Pfizer or its designee regarding (1) filings and communications with any Regulatory Authority, (2) patient advocacy and support, and (3) pharmacovigilance activities, in each case, in Israel with respect to the Drug Substance or the Licensed Product; provided that [***]. For purposes of clarification, Protalix is not obligated to pursue additional indications and/or submissions in Israel other than required modifications due to those related to safety under the current, Protalix marketing authorization.

(j) Communications with Regulatory Authorities Outside the Territory. Until any marketing authorization application for Licensed Product submitted by Protalix or its designee Fiocruz (or such other applicable sublicensee) is approved by the National Sanitary Surveillance Agency of the Brazilian Government (or any successor or replacement agency that has the authority to grant the necessary Regulatory Approvals) and any other required Regulatory Approval is obtained by Protalix or its designee Fiocruz (or such other applicable sublicensee), and with respect to any Pfizer or Pfizer Affiliate Regulatory Approvals and regulatory filings (including marketing authorizations) in Brazil and related data:

(i) Pfizer shall provide Protalix notice of all meetings, conferences, and discussions (including meeting of experts convened by any Regulatory Authority in Brazil concerning any topic relevant to the Licensed Product) scheduled with any Regulatory Authority in Brazil concerning any regulatory matters relating to the Licensed

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

Product promptly after the scheduling of such meeting, conference, or discussion (to the extent Pfizer is made aware of them in advance). Protalix or its designee Fiocruz (or such other applicable sublicensee) shall be entitled to have one or more representatives present at all such meetings unless prohibited by applicable Law or unless reasonably impracticable under the circumstances. Protalix or its designee Fiocruz (or such other applicable sublicensee) and Pfizer shall use all reasonable efforts to agree in advance on the scheduling of such meetings, conferences and discussions and on the objectives to be accomplished at such meetings, conferences and discussions and the agenda for the meetings, conferences and discussions with such Regulatory Authority; provided that [***];

(ii) Pfizer shall provide Protalix or its designee Fiocruz (or such other applicable sublicensee) with copies, which copies may be in draft form, of all material submissions to any Regulatory Authority in Brazil relating to the Licensed Product, to be provided sufficiently in advance of such planned submission to such Regulatory Authority in order to allow Protalix or its designee Fiocruz (or such other applicable sublicensee) to provide comments regarding such submission, which comments shall be considered by Pfizer in good faith with respect to such submission; provided that [***];

(iii) Pfizer and Protalix (or Protalix's designee Fiocruz (or such other applicable sublicensee)) shall provide to the other, as soon as reasonably practicable but in no event more than three (3) Business Days after its receipt, copies of any material documents or other material correspondence received from any Regulatory Authority in Brazil; and

(iv) Pfizer shall reasonably cooperate with Protalix and its Affiliates or its designee Fiocruz (or such other applicable sublicensee) regarding (1) filings and communications with any Regulatory Authority, (2) patient advocacy and support, and (3) pharmacovigilance activities, in each case, in Brazil with respect to the Drug Substance or the Licensed Product; provided that [***]. For purposes of clarification, Pfizer is not obligated to pursue additional indications and/or submissions in Brazil other than required modifications due to those related to safety under the current, Pfizer marketing authorization.

(k) [Reserved].

(l) Recalls or Other Corrective Action.

(i) Pfizer shall promptly notify Protalix of any material actions to be taken by Pfizer in the Territory 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 Protalix a reasonable opportunity to consult with Pfizer with respect thereto. [***]

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

(ii) Protalix shall promptly notify Pfizer of any material actions to be taken by Protalix outside the Territory 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 Pfizer a reasonable opportunity to consult with Protalix with respect thereto.

4.2 Commercialization and Pricing.

(a) Pfizer shall have the sole authority and exclusive right to Commercialize, and shall be responsible for paying all costs and expenses (except as otherwise expressly set forth in this Agreement) associated with the Commercialization of, the Licensed Product in the Field in the Territory, including marketing, promoting, selling, distributing and [***] for the Licensed Product and obtaining any necessary Price Approvals. Protalix hereby agrees to refrain from selling Licensed Product outside the Territory to any Person if Protalix has knowledge or reason to believe that such Licensed Product is intended for transshipment or delivery by such Person in the Territory. Pfizer hereby agrees to refrain from selling the Licensed Product in the Territory to any Person if Pfizer has knowledge or reason to believe that such Licensed Product is intended for transshipment or delivery by such Person outside the Territory.

(b) Notwithstanding anything to the contrary in Section 4.2(a), Protalix shall continue to Commercialize the Licensed Product in the Field in Israel following the Second Amendment Effective Date until such time that Pfizer has received the necessary Regulatory Approvals for Pfizer to commence Commercialization of the Licensed Product in the Field in Israel, but in no event extending longer than [***] after the Second Amendment Effective Date (the "Israel Transition Period"), and during the Israel Transition Period, (i) Protalix shall not materially alter its usual activities and practices with respect to inventory levels (including samples) of the Licensed Product maintained at the wholesale, pharmacy or institutional levels in Israel, without the consent of the Transition Team, (ii) Protalix shall not take any non-routine action that deviates from the ordinary course of business with respect to the Commercialization of the Licensed Product in the Field in Israel without consulting with the Transition Team, and (iii) Protalix shall inform the Transition Team of any allegations, inquiries, or investigations of violations of Protalix's policies or Laws related to commercialization of the Licensed Product in Israel. Pfizer shall provide Protalix written notice immediately upon becoming aware that Pfizer has received the necessary Regulatory Approvals for Pfizer to commence Commercialization of the Licensed Product in the Field in Israel. Pfizer shall consider in good faith whether to continue to participate in any [***] at the end of the Israel Transition Period.

(c) Following the Second Amendment Effective Date, Pfizer shall purchase all remaining finished goods inventories of Licensed Product relating to Israel [***]. Such shipment shall be accompanied by a Manufacturing Certificate of Analysis and shall be subject to Sections 5.10(a) through (d), and such invoice shall be payable to Protalix within forty-five (45) days of receipt of the invoice. Any disputes with respect to such invoice shall be escalated to the Transition Team for resolution. If the Transition Team is unable to resolve such dispute, then such dispute shall be escalated to the Supply Chain Committee to resolve pursuant to Section 5.1.

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

4.3 Protalix Trademarks. Protalix hereby grants to Pfizer a license to use any trademarks (including Protalix's name or trade names) Controlled by Protalix solely for the purposes of selling, and solely to the extent reasonably necessary to sell, the Inventories in Israel pursuant to Section 4.2(c), subject to quality control provisions substantially equivalent to those set forth in Section 4.4(d), which shall apply mutatis mutandis hereto.

4.4 Pfizer Trademarks.

(a) Assignment. The parties acknowledge that Protalix transferred and assigned to Pfizer all of its worldwide rights, title and interest to the Uplyso Trademarks, including any goodwill associated with such Uplyso Trademarks. Pfizer shall be responsible for paying all costs and expenses associated with recording the trademark assignment instrument with the appropriate governmental authorities throughout the world.

(b) Choice of Trademarks. Pfizer may choose, in its sole discretion, to use the Uplyso Trademarks or any other trademarks to Commercialize the Licensed Product in the Field in the Territory and Pfizer shall own all such trademarks (collectively, the "Product Marks").

(c) License to Protalix. Pfizer hereby grants to Protalix an exclusive license, free of charge, to use the Brazil Uplyso Trademark and any other Product Marks required by applicable Laws to be included on the labeling and packaging of the finished packaged product outside the Territory solely in connection with the packaging, sale, marketing, promotion, advertising, disposition and distribution of the Licensed Product in the Field outside the Territory. Pfizer acknowledges and agrees that Protalix is permitted to sublicense to Fiocruz (or any other sublicensee of Protalix in Brazil) the Brazil Uplyso Trademark and any other Product Marks required by applicable Laws to be included on the labeling and packaging of the finished packaged product outside the Territory as set forth in Section 3.6(c). For the avoidance of doubt, the rights granted pursuant to this Section 4.4(c) do not include grants to use the name or trade name of Pfizer (other than to the extent such right is granted to Protalix pursuant to Section 4.5 or required to be made pursuant to Section 4.4(d)(iv)(B)). Any such right to use such name or trade name shall be governed by Section 4.5.

(d) Quality Control.

(i) The quality of the Licensed Product sold by Protalix outside the Territory under or in connection with the Brazil Uplyso Trademark (and any Product Marks licensed to Protalix pursuant to Section 3.6(c) and Section 4.4(c)) must be of a sufficiently high quality to be generally comparable to the quality of the Licensed Product sold by Pfizer in the Territory under or in connection with the Product Marks.

(ii) Protalix shall comply with all applicable Laws pertaining to the proper use and designation of the Brazil Uplyso Trademark (and any Product Marks licensed to Protalix pursuant to Section 3.6(c) and Section 4.4(c)).

(iii) Protalix agrees to use the Brazil Uplyso Trademark (and any Product Marks licensed to Protalix pursuant to Section 3.6(c) and Section 4.4(c)) only in the form and manner and with appropriate legends as prescribed from time to time by Pfizer.

(iv) Additionally, Protalix shall:

(A) display the proper form of trademark notice associated with the Brazil Uplyso Trademark (and any Product Marks licensed to Protalix pursuant to Section 3.6(c) and Section 4.4(c));

(B) on any item which bears the Brazil Uplyso Trademark (and any Product Marks licensed to Protalix pursuant to Section 3.6(c) and Section 4.4(c)), include where practicable a statement identifying Pfizer or its Affiliate, as applicable, as the owner of the Brazil Uplyso Trademark or Product Mark and where possible indicating that Protalix or its Affiliate, as applicable, is an authorized user of the Brazil Uplyso Trademark or Product Mark;

(C) not use any Product Mark as a corporate name, business name, or trade name;

(D) not use any Product Mark in a manner that would reasonably be expected to materially impair the validity, reputation, or distinctiveness of any Product Mark; and

(E) not use any Product Mark in a manner that would reasonably be expected to materially impair the reputation of Pfizer or any of its Affiliates.

(e) Prosecution and Maintenance of Product Marks. Pfizer 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 the first right, but not the obligation, through counsel of its choosing, to prosecute and maintain the Product Marks outside the Territory. In the event Pfizer elects not to prosecute or maintain the Brazil Uplyso Trademark outside the Territory, Pfizer shall provide reasonable prior written notice to Protalix of its intention not to prosecute or maintain any such Product Mark outside the Territory, and Protalix shall have the right to prosecute or maintain the Brazil Uplyso Trademark on behalf of Pfizer. All costs and expenses incurred by Pfizer in the filing, prosecution and maintenance of Product Marks in the Territory shall be [***]. All costs and expenses incurred by either party in the filing, prosecution and maintenance of Product Marks (in the case of Pfizer) or the Brazil Uplyso Trademark outside the Territory as provided in this Section 4.4(e) shall be [***].

(f) Enforcement of Product Marks.

(i) Pfizer will promptly notify Protalix in the event of any actual, potential or suspected infringement of the Brazil Uplyso Trademark by any Third Party and Protalix will promptly notify Pfizer in the event of any actual, potential or suspected infringement of the Brazil Uplyso Trademark or a Product Mark by any Third Party. Pfizer 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 the first right, but not the obligation, to institute litigation or take other

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

remedial measures in connection with Third Party infringement of Product Marks outside the Territory. If Pfizer fails to initiate litigation or take other remedial measures against a Third Party who is infringing the Brazil Uplyso Trademark outside the Territory within ninety (90) days after becoming aware of the basis for such litigation or action, then Protalix may, in its discretion, provide Pfizer with written notice of Protalix's intent to initiate a suit or take other appropriate action. If Protalix provides such notice and Pfizer fails to initiate litigation or take such other appropriate action within thirty (30) days after receipt of such notice from Protalix, then Protalix shall have the right to initiate litigation or take other appropriate action that it believes is reasonably required to protect its right to use the Brazil Uplyso Trademark outside the Territory. Upon request of Protalix, Pfizer agrees to timely join as party-plaintiff in any such litigation, and in any event to cooperate with Protalix in connection with such infringement action. All costs and expenses incurred by Pfizer in enforcing the Product Marks in the Territory shall be borne by Pfizer and any recoveries resulting from such litigation or other appropriate action, in pursuing such litigation or other appropriate action, shall be retained by Pfizer. All costs and expenses incurred by Protalix in enforcing the Brazil Uplyso Trademark outside the Territory shall be [***] and Protalix shall reimburse Pfizer for any and all costs or expenses incurred by Pfizer in connection with such enforcement by Protalix outside the Territory. Protalix shall retain all recoveries received by Protalix as a result of its enforcement of the Brazil Uplyso Trademark outside the Territory.

4.5 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, Protalix shall have the right to use the Pfizer corporate name, subject to Pfizer's trademark usage guidelines provided to Protalix from time to time, including at least sixty (60) days prior to the date of Protalix's first use of the Pfizer corporate name, on package inserts, packaging or trade packaging associated with the Licensed Product outside the Territory solely as required by applicable Laws outside the Territory. Protalix will submit for Pfizer's approval (which approval shall not be unreasonably withheld or delayed) a sample of each such proposed use of the Pfizer corporate name within sixty (60) days before the first use permitted pursuant to this Section 4.5. Notwithstanding anything to the contrary in this Section 4.5, Pfizer shall have the right to use the name of Protalix or its Affiliates or any other trade name of Protalix pursuant to and in accordance with Section 4.3.

4.6 Access to Information. At Pfizer's reasonable request during the Term, Protalix shall provide Pfizer, its designated Affiliate or its agents and representatives with reasonable access [***], during regular business hours to (a) information concerning the Drug Substance, Licensed Product, Protalix Patent Rights and/or Protalix Technology that may be reasonably necessary for Pfizer to seek Regulatory Approval for Licensed Product, Manufacture (including performing Fill/Finish activities on) the Drug Substance or the Licensed Product or Commercialize the Licensed Product, in each case, in the Field in the Territory and (b) Protalix-designated employees who possess the information described in clause (a) of this Section 4.6, in each case, solely for the purpose of enabling Pfizer to exercise the licenses granted to Pfizer

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

hereunder. Such requested cooperation and assistance shall be provided at no cost to Pfizer, except that [***]

4.7 Transition Assistance. During the Transition Period, each party shall use Commercially Reasonable Efforts to cooperate with the other party and to take such reasonable actions to assist the other party, as the other party may reasonably request, (i) to ensure the smooth transition of the Commercialization of the Drug Substance or Licensed Product from Protalix to Pfizer (or a Third Party designated by Pfizer) in Israel and from Pfizer to Protalix (or a Third Party designated by Protalix) in Brazil, and (ii) to ensure the continuity of patient care in Brazil and Israel. Except as set forth in this Agreement, the parties shall no longer have any obligations under the Agreement to Commercialize or Develop the Licensed Product, conduct any pre-clinical or clinical studies or participate in any committees with the other party other than the Supply Chain Committee and the Transition Team.

(a) Transition Team. Within five (5) days following the Second Amendment Effective Date, Pfizer and Protalix shall each appoint a person (each a "Transition Manager" and together, the "Transition Team") to facilitate a smooth transition of the Commercialization of the Drug Substance or Licensed Product from Protalix to Pfizer (or a Third Party designated by Pfizer) in Israel and from Pfizer to Protalix (or a Third Party designated by Protalix) in Brazil, and to implement the Transition Plan (as defined below). Each party shall notify the other party in writing of the identity and contact information for their respective Transition Manager, which shall be the primary contact for each party with respect to the transition and the Transition Plan and all activities thereunder. For [***] following the Second Amendment Effective Date (the "Transition Period"), the Transition Managers shall meet (in person, by teleconference, video-conference or other reasonable means, in each case as mutually agreed upon by the Transition Managers) as reasonably necessary, but not less frequently than a weekly basis, as mutually agreed upon by the Transition Managers to facilitate the implementation of the Transition Plan. In the event that the Transition Plan has not been implemented within [***] following the Second Amendment Effective Date, the parties shall mutually agree in good faith on a new Transition Period, and following such agreement the term Transition Period shall refer to such new period as so agreed upon by the parties.

(b) Transition Plan. In connection with the transition of Israel and Brazil, during the Transition Period, the parties shall use Commercially Reasonable Efforts to accomplish all of the transition activities described in Exhibit F to effect a reasonably smooth and orderly transition (the "Transition Plan"). Pfizer and Protalix will commence delivery of the items specified in the Transition Plan as soon as reasonably practicable and shall use Commercially Reasonable Efforts to meet the timelines specified in the Transition Plan.

4.8 Records. Each party will maintain accurate records and books relating to its activities in relation to the Development of the Drug Substance and the Licensed Product, including any activities conducted under the Development plans between the parties pursuant to the Amended Agreement.

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

Section 5. MANUFACTURE AND SUPPLY.

5.1 Supply Chain Committee.

(a) Formation and Membership. The parties shall continue to maintain a Supply Chain Committee (the "Supply Chain Committee") during the Supply Term. The Supply Chain Committee shall consist of representatives appointed by each party. The Supply Chain Committee will provide a forum for the discussion of matters related to the Manufacture of and supply chain for the Drug Substance and Licensed Product.

(b) Meetings. During the Supply Term, the Supply Chain Committee shall meet monthly or as otherwise determined by the parties (each such meeting, a "Supply Chain Committee Meeting"). Upon the request of the Supply Chain Committee, each party will provide written materials relating to its Manufacturing and related activities in advance of a Supply Chain Committee Meeting. All Supply Chain Committee Meetings may be conducted in person, by videoconference or by teleconference at such times and such Pfizer or Protalix locations as shall be determined by the Supply Chain Committee. In-person meetings of the Supply Chain Committee 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 Supply Chain Committee. The members of the Supply Chain 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. The Supply Chain Committee will have the following roles and responsibilities:

(i) Discuss each party's requirements for Drug Substance and Licensed Product for Development activities in accordance with Section 5.3;

(ii) Act as a forum pursuant to which the parties may discuss Manufacturing issues, and any issues that may affect patient access to the Licensed Product in the Territory;

(iii) Be informed of requests for and results of regulatory inspections related to Drug Substance and Licensed Product and review steps to be taken by Protalix to address any deficiencies noted;

(iv) Monitor logistical strategies, Protalix's capacity for Manufacturing Drug Substance and inventory levels for Drug Substance and Licensed Product for consistency with the Forecasts and Long Range Forecasts and address any Failure to Supply and Persistent Failure to Supply;

(v) Be informed of and discuss proposed changes in Manufacturing sites, testing sites, and responsibilities in the supply chain for Drug Substance and Licensed Product;

(vi) Be informed of and address any quality-related issues concerning the Drug Substance and Licensed Product including non-conformance;

(vii) Provide updates on the Supply Chain Committee's activities and achievements to the parties, as applicable, no less frequently than once each quarter after the Second Amendment Effective Date; and

(viii) Such other roles and responsibilities provided for in this Agreement or as may be assigned to the Supply Chain Committee in writing by mutual agreement of the parties.

(d) Decision-Making. Except for a decision to create a Technical Subcommittee as described in Section 5.1(e), the Supply Chain Committee will have no decision-making authority, but instead will act in an advisory capacity to the parties, unless otherwise agreed by the parties in writing.

(e) Technical Subcommittee. The Supply Chain Committee may, from time to time, create a subcommittee (a "Technical Subcommittee") to advise the Supply Chain Committee and the parties on and analyze any technical issues relating to Manufacturing Drug Substance or Licensed Product, including issues relating to quality or process, identified by either party or by the Supply Chain Committee. Any Technical Subcommittee shall consist of representatives from each party with the appropriate technical expertise to analyze and provide advice with respect to any such technical issues, and such representatives may or may not also be representatives on the Supply Chain Committee. Each Technical Subcommittee will continue to operate until resolution of the identified problem, as determined by the Supply Chain Committee. If the Supply Chain Committee is unable to reach agreement with respect to the issue identified by the Supply Chain Committee, Pfizer's Vice President of Global External Supply and Protalix's Chief Operating Officer will meet promptly to attempt to resolve the dispute by good faith negotiations.

5.2 Capacity.

(a) Protalix shall [***].

(b) [***] Along with such request, Pfizer shall [***]If Protalix determines [***] Protalix shall [***] Pfizer and Protalix shall agree [***] Pfizer shall [***] Notwithstanding the foregoing, in no case shall Protalix [***] Pfizer shall [***] Protalix shall [***]

(c) Protalix shall dedicate at least [***] of its Drug Substance Manufacturing capacity in order to Manufacture Drug Substance for Pfizer's clinical and commercial use in the Field in the Territory and may dedicate all remaining capacity to Manufacture Drug Substance for Protalix's clinical and commercial use in the Field outside the Territory (such allocation between the Territory and outside the Territory, the "Allocation Percentage"). Subject to the Current Capacity Cap or, after achieving the Increased Capacity Goal, the Increased Capacity Cap (collectively, the "Capacity Cap"), subject to the Allocation Percentage, and subject to and in accordance with the terms of this Section 5 and the Quality Agreement, Protalix shall supply all quantities of the Drug Substance ordered by Pfizer under this Agreement for clinical and commercial use in the Field in the Territory.

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

(d) In the event either party reasonably believes that capacity for the Manufacture of Drug Substance in excess of the Increased Capacity Cap is necessary to meet projected future clinical and commercial need for Licensed Product in the Territory, the parties shall discuss such matter in good faith, including the funding of any capital expenditures necessary to increase such Manufacturing capacity beyond the Increased Capacity Cap.

5.3 Development Supply of Drug Substance. Subject to the Capacity Cap and the Allocation Percentage, Protalix shall Manufacture and supply Pfizer's requirements of the Drug Substance for incorporation into Licensed Product for Development activities to be performed by Pfizer in the Field in the Territory, which supply shall be subject to and in accordance with the terms of this Section 5. For the avoidance of doubt, in no event shall Protalix be obligated to Manufacture or supply quantities of Drug Substance in excess of the Capacity Cap unless otherwise agreed by the parties.

5.4 Commercial Supply of Drug Substance. Subject to the Capacity Cap and the Allocation Percentage, Protalix shall Manufacture and supply Pfizer's requirements of the Drug Substance for incorporation into Licensed Product and commercial sale in the Field in the Territory pursuant to this Agreement, which supply shall be subject to and in accordance with the terms of this Section 5 and the Quality Agreement. For the avoidance of doubt, in no event shall Protalix be obligated to Manufacture or supply quantities of Drug Substance in excess of the Capacity Cap unless otherwise agreed by the parties.

5.5 Supply Term. The terms of this Section 5 shall be effective as of the Second Amendment Effective Date and, unless this Agreement is earlier terminated pursuant to Section 14, shall remain in effect only until terminated in accordance with this Section 5 (the "Supply Term"). The initial term for the supply of Drug Substance under this Section 5 shall be for ten (10) years after the Second Amendment Effective Date (the "Initial Supply Term"). If Protalix determines not to extend the supply of Drug Substance to Pfizer hereunder beyond such Initial Supply Term, Protalix shall have the right to provide written notice of termination of the Supply Term, at least three (3) years prior to the effective date of termination of the Supply Term set forth in such notice (which shall in no event be prior to the end of the Initial Supply Term) (the "Supply Termination Notice"); provided that notwithstanding the timely issuance of a Supply Termination Notice by Protalix in accordance with the foregoing sentence Pfizer shall have the right to extend the Supply Term for up to two additional periods of thirty (30) months each (each, a "Renewal Supply Term") by providing to Protalix a written extension notice at least one (1) year prior to the end of the Initial Supply Term or the first Renewal Supply Term, as applicable (with the first Renewal Supply Term commencing at the end of the Initial Supply Term and the second Renewal Supply Term commencing at the end of the first Renewal Supply Term). For the avoidance of doubt, (i) in the event Pfizer does not provide a written extension notice at least one (1) year prior to the end of the Initial Supply Term in accordance with the foregoing sentence, the Supply Term shall terminate upon the stated effective date of termination in the Supply Termination Notice, (ii) in the event Pfizer provides a written extension notice for the first Renewal Supply Term in accordance with the foregoing sentence, but does not provide a written extension notice for the second Renewal Supply Term at least one (1) year prior to the end of the first Renewal Supply Term in accordance with the foregoing sentence, the Supply Term shall terminate upon the end of the first Renewal Supply Term, and (iii) in the event Pfizer provides a written extension notice for the first and second Renewal Supply Terms in accordance

with the foregoing sentence, the Supply Term shall terminate fifteen (15) years after the Second Amendment Effective Date.

5.6 Forecasting and Ordering.

(a) Forecasts; Purchase Orders. [***], Pfizer shall deliver to Protalix Pfizer's quarterly projection of the quantities of Drug Substance that Pfizer anticipates ordering from Protalix pursuant to this Agreement for the four (4) calendar quarters commencing with the first quarter that includes the first requested delivery date (the "Initial Forecast"), together with a firm purchase order (a "Purchase Order") for Drug Substance for the first calendar quarter covered by such Initial Forecast. The quantities of Drug Substance specified for the following quarter of such Initial Forecast shall be binding as provided in this Section 5.6 and the remaining two (2) quarters of such Initial Forecast shall be non-binding. Thereafter, ninety (90) days prior to the first business day of each subsequent calendar quarter during the Term, Pfizer shall deliver to Protalix a rolling four (4) calendar quarter forecast updating the prior forecast (together with the Initial Forecast, each a "Forecast"), together with a Purchase Order for the first calendar quarter of such Forecast. The quantities of Drug Substance specified for the following quarter of such Forecast shall be binding as provided in this Section 5.6 and the remaining two (2) quarters of such Forecast shall be non-binding. Unless agreed separately between the parties, each Purchase Order shall specify no more than three (3) delivery dates for the Drug Substance in each calendar quarter. Purchase Orders shall be in writing, and no verbal communications or e-mail shall be construed to mean a commitment to purchase or sell. Each Purchase Order delivered by Pfizer to Protalix pursuant to this Section 5.6(a) shall be binding on Protalix to the extent provided by Section 5.6(c). Protalix shall confirm receipt of any [***].

(b) Long Range Capacity Planning. Concurrent with the Initial Forecast, for the purposes of discussion and planning of Manufacturing capacity, Pfizer shall provide a non-binding forecast of its projected Drug Substance needs for the eight (8) calendar quarters following that specified in the Initial Forecast as described in Section 5.6(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 Substance reflected in a Long Range Forecast, Protalix shall promptly notify Pfizer and the Supply Chain Committee shall work to remedy the shortfall in accordance with and subject to the terms of this Section 5 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 Pfizer annually by July 1 of each calendar year during the Term.

(c) Maximum Quantities. Unless otherwise agreed in writing by Protalix, in no event shall Protalix be obligated to deliver quantities of Drug Substance [***] The foregoing limitation shall be in addition to the Capacity Cap. Protalix shall, however, use Commercially Reasonable Efforts, but will be under no obligation, to supply Drug Substance [***].

(d) Minimum Quantities. If the quantities of Drug Substance specified in a Purchase Order for a quarter are less than [***] of the quantities specified by Pfizer for the same

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

period in the Forecast delivered [***], then, at the election of Pfizer set forth in a notice which Pfizer shall deliver to Protalix within [***], (i) Protalix shall, [***]

(e) Receipt and Acceptance. Subject to Sections 5.6(c) and 5.6(d), Pfizer shall purchase all Drug Substance 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 5.6(e) 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 18.9.

5.7 Pricing and Invoicing.

(a) Supply Delivery Price. [***]

(b) Invoices. Following the release of the Drug Substance subject to the Purchase Order hereunder and the submission to Pfizer of the Manufacturing Certificate of Acceptance and the Certificate of Compliance (as defined in the Quality Agreement) relating to such released Drug Substance, each delivery of Drug Substance under a Purchase Order hereunder shall be accompanied by an invoice. Protalix shall invoice Drug Substance at [***] 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. [***]

(c) Taxes. All sales and use taxes which Protalix is required by law to collect from Pfizer with respect to the Manufacture and supply of Drug Substance to Pfizer shall be separately stated in Protalix's invoice and shall be paid by Pfizer to Protalix unless Pfizer provides an exemption to Protalix. Protalix shall be solely responsible for the timely payment of all such taxes to the applicable taxing authority, and Protalix shall pay (without reimbursement by Pfizer), and shall hold Pfizer harmless against, any penalties, interest or additional taxes that may be levied or assessed as a result of the failure or delay of Protalix to pay any such taxes.

5.8 Shipping and Delivery.

(a) Storage. Protalix shall maintain dedicated freezer storage (i.e., freezers that is used only to store Drug Substance manufactured for Pfizer) for Drug Substance manufactured but not yet delivered to Pfizer pursuant to a Purchase Order. Such dedicated freezers shall be maintained in compliance with cGMP requirements and shall be stored in a secure area to prevent unauthorized access and/or manipulation. Procedures shall be in place for reporting and neutralizing unauthorized entry into such dedicated freezers.

(b) Delivery. Subject to Section 5.5, Protalix shall deliver (or have delivered) to Pfizer in accordance with this Section 5.8 the quantities of the Drug Substance specified for a given delivery date in each Purchase Order with, in the case of Drug Substance, no less than:

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

[***] Such decision by the Supply Chain Committee shall be intended to ensure sufficient supply of Drug Substance meeting the requirements of the applicable Regulatory Authorities and Regulatory Approvals throughout the Territory. If the Supply Chain Committee determines to increase the Minimum Shelf Life, then the Minimum Shelf Life shall be increased by [***] of such approved increase in shelf life. All dates for delivery of Drug Substance are [***]

(c) Delivery Terms. The Drug Substance shall be supplied to Pfizer [***]. The Drug Substance shall be shipped [***]. Pfizer shall be responsible for[***] For the avoidance of doubt, title and risk of loss shall not transfer to Pfizer until the Drug Substance is delivered to Pfizer or its designee in accordance with this Section 5.8(c).

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

5.9 Compliance; Quality Control Obligations.

(a) The parties shall determine if the Quality Agreement needs to be updated, and if necessary, shall update the Quality Agreement within sixty (60) days following the Second Amendment Effective Date. The Quality Agreement shall set forth the parties' compliance obligations with respect to the Drug Substance Manufactured by Protalix for clinical and commercial requirements in the Territory. To the extent there are any inconsistencies or conflicts between this Agreement and the Quality Agreement with respect to quality issues, the terms and conditions of the Quality Agreement shall control.

5.10 Certificate of Analysis; Acceptance and Returns.

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

(i) Following Manufacture. Following the release of the Drug Substance subject to an applicable Purchase Order by Protalix and before issuing an invoice for such Drug Substance pursuant to Section 5.7(b), Protalix shall supply to Pfizer the applicable batch number for the Drug Substance, and such other information as the parties may set forth in the Quality Agreement with respect to the Manufacture (a "Manufacturing Certificate of Analysis") for such Drug Substance.

(ii) Following Delivery. Pfizer shall (within the time period specified in Section 5.10(b)) inspect, or cause to have inspected, each shipment of the Drug Substance for any damage, defect or shortage and give Protalix written notice of any such damaged, defective or short shipment (a "Notice of Non-Conformance") within the time periods specified in Sections 5.10(a)(iii) and 5.10(b), as applicable.

(iii) 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 Pfizer or was notified to Pfizer by the relevant party discovering the defect.

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

(b) Rejection. Pfizer shall have [***] following its receipt of each shipment of the Drug Substance to inspect such shipment. If Pfizer determines that any shipment of the Drug Substance does not conform to the Product Specifications (or is otherwise a short shipment), it shall promptly notify Protalix within [***] following such determination in compliance with the procedures set forth in the Quality Agreement.

(c) Disputes. If Pfizer delivers a Notice of Non-Conformance in respect of all or any part of a shipment of the Drug Substance, and Protalix does not agree with Pfizer's determination that such shipment fails to meet the Product Specifications (or is otherwise a short shipment), the parties shall in good faith attempt to resolve such dispute at the Supply Chain Committee. Protalix and Pfizer shall have 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 Manufactured in conformance with the Product Specifications (or was otherwise a short shipment). If the dispute regarding whether all or any part of a shipment rejected by Pfizer was Manufactured in conformance with the Product Specifications (or was otherwise a short shipment) is not resolved in such thirty (30) day period, then [***]

(d) Destruction. In the event any shipment of Drug Substance is rejected pursuant to this Section 5.10 as a result of any act or omission of Protalix, then Pfizer shall, at the direction of Protalix, either (x) destroy such rejected Drug Substance or Licensed Product at Protalix's expense (in accordance with applicable Law) or (y) return such rejected Drug Substance or Licensed Product to Protalix, at a location designated by Protalix and at Protalix's expense; provided that if Protalix requests the return of such rejected Drug Substance or Licensed Product, Protalix shall not use such Drug Substance or Licensed Product for any purpose, shall destroy such rejected Drug Substance or Licensed Product and certify to Pfizer that it has destroyed such rejected Drug Substance or Licensed Product.

(e) Refund, Replacement of Non-Conforming Product. Pfizer may return to Protalix at Protalix's expense any Drug Substance rejected pursuant to this Section 5.10 as a result of any act or omission of Protalix, its Affiliates or their respective agents, vendors, suppliers or subcontractors. In addition to any other rights or remedies of Pfizer hereunder, Protalix shall at Pfizer's sole discretion (i) replace any Drug Substance rejected by Pfizer, at no additional cost to Pfizer, as soon as reasonably practicable on an expedited basis; or (ii) provide a credit or refund to Pfizer for the full amount invoiced to and paid by Pfizer for such Drug Substance.

(f) Shortages. In the event that the materials and/or Manufacturing capacity required by Protalix to Manufacture and to deliver to Pfizer the Drug Substance required as specified in Purchase Orders are in short supply, Protalix shall notify Pfizer of such shortage and the Supply Chain Committee shall promptly meet to discuss the shortage. Protalix shall provide to the Supply Chain 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, including using all capacity at its Facility to Manufacture Drug Substance (including stopping the

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

manufacture of all other products at the Facility for sales by Protalix or Third Parties). During any such shortage, Protalix shall allocate the materials and resources used in the supply of the Drug Substance such that Pfizer receives [***] of the Drug Substance for the Territory and Protalix receives [***] of the Drug Substance for outside the Territory.

5.11 Product Specification and Manufacturing Changes. Product Specification and Manufacturing changes, including those resulting from a request received by a 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 4.

5.12 Change Control. Protalix shall not make any changes to its process, raw materials, supply sources, manufacturing locations or facilities (including Drug Substance storage facilities and equipment) used to make Drug Substance for Pfizer under this agreement, including any such changes that may require Pfizer to provide notification to Regulatory Authorities, except to the extent permitted under the Quality Agreement.

5.13 Practices. Protalix shall comply with current Good Manufacturing Practices (cGMP) as it applies to receipt, storage, handling and control of materials and the Drug Substance.

5.14 Pest Control. Protalix shall manufacture and store Drug Substance, and shall store all ingredients, raw materials and components used to manufacture Drug Substance, in a clean, dry area, free from insects and rodents, in a manner to prevent entry of foreign materials and contamination of Drug Substance. Protalix's pest control measures shall include adequate cleaning of the facility, control of food and drink, protection of Drug Substance from the environment, monitoring of flying and crawling pests, and logs detailing findings and actions taken. Protalix's pest control program shall be described in a written procedure subject to review and approval of Pfizer. Failure of Protalix to comply with this Section 5.14 shall be deemed a material breach of this Agreement.

5.15 Records and Audits. Protalix shall maintain complete and accurate records of all matters relating to the Manufacturing of Drug Substance that enable Protalix to demonstrate compliance with its obligations under this Agreement, including Protalix's compliance with applicable Laws, in accordance with the terms of the Quality Agreement. As used in this Section 5.15, records include all books, documents, and other data specified in the Quality Agreement regardless of type or form. Protalix shall maintain such records for the period of time set forth in the Quality Agreement. Pfizer or its representatives may (at Pfizer's sole cost and expense), subject to the confidentiality provisions in Section 9, audit such records of Protalix in accordance with the terms of the Quality Agreement at any time during the Supply Term and for the [***] period following the expiration or termination of (x) the Supply Term or (y) the last Purchase Order in effect, whichever occurs later, during normal business hours and upon reasonable advance written notice to Protalix. Protalix shall make such records readily available for such audit, and Pfizer or its representatives may copy any and all such records in connection with any such audit.

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

5.16 Quality Assurance. Protalix shall have a formal quality assurance program and appropriate written quality control procedures covering its operations.

5.17 Technical Support. Protalix shall provide means for Pfizer to contact Protalix's service representative twenty-four (24) hours a day, seven (7) days a week during the Supply Term.

5.18 Technical Assistance; Facility Access.

(A) Pfizer shall have the right to provide technical assistance and advice to Protalix on an ongoing basis, including in-person at Protalix's Facility;

(B) Pfizer may physically inspect Protalix's Facility, including being present during Manufacturing operations, quality control, quality assurance, pack out and shipping;

(C) Protalix shall provide Pfizer with reasonable ongoing access to its Facility and all relevant Manufacturing records and personnel (wherever located) of Protalix and will use Commercially Reasonable Efforts to facilitate access to any Third Party suppliers of materials for the Drug Substance; and

(D) Protalix shall reasonably cooperate with Pfizer and its representatives in connection with the activities described above and, upon mutual agreement of the parties as to any deficiencies, Protalix shall use its Commercially Reasonable Efforts to promptly correct any such deficiencies if and to the extent mutually agreed by the parties.

Pfizer and its representatives shall carry out the activities described in this Section 5.18 during Protalix's regular business hours at times reasonably agreed upon by Pfizer and Protalix, with as minimal disruption to Protalix's operations as reasonably practicable [***]. Such requested cooperation and assistance pursuant to Sections 5.18(C) and 5.18(D), shall be provided [***]

5.19 Other Assistance by Pfizer. Protalix acknowledges that Pfizer has expertise with respect to manufacturing and pharmaceutical sciences and is able to provide assistance to Protalix in the following areas: (a) registering with the FDA and EMEA a manufacturing technology for commercial supply of Drug Substance, including the preparation of a complete, approvable chemistry, manufacturing, and controls section of an NDA and other regulatory filings packages, (b) the regulatory review process, (c) addressing regulatory review feedback or post-approval requirements by any Regulatory Authority, (d) bioprocess, analytical or formulation development, (e) validation, (f) characterization and stability studies, (g) preparing for and supporting pre-approval inspections; and (h) preparing Protalix's Facility to make it suitable for Regulatory Approval, including finalizing any required changes to the facility or equipment train, IQ/OQ/PQ, and equipment cleaning and cleaning validation (collectively, the "Advisory Services"). At any time during the Term, Pfizer shall have the right to provide

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

Advisory Services to Protalix and upon reasonable advance written notice from Pfizer, Protalix shall reasonably consider in good faith the recommendations of Pfizer with respect to such Advisory Services. Pfizer shall be responsible for and bear [***] of the costs and expenses it incurs in providing Advisory Services to Protalix.

5.20 Master Cell Bank. During the Term, Protalix shall, as the supplier of Drug Substance, maintain half of the master cell bank relating to the Drug Substance in a location selected by Protalix and the other half of the master cell bank relating to the Drug Substance at a different location selected by Protalix and approved by Pfizer (such approval not to be unreasonably withheld or delayed), which may include the Facility where Pfizer performs Fill/Finish activities (provided that Pfizer obtains all required approvals from the applicable Regulatory Authority necessary to store the master cell bank in such Facility).

5.21 [***]

5.22 [***]

5.23 Manufacturing Transition Assistance. Upon Pfizer's request, in order to ensure continuity of supply of the Drug Substance following expiration or termination of this Agreement or Pfizer's election to exercise its right to Manufacture or have a Third Party Manufacture the Drug Substance, Protalix shall provide reasonable assistance to Pfizer in arranging for the Manufacture of the Drug Substance by Pfizer or by an alternative supplier chosen by Pfizer, including providing technical consulting services to Pfizer or such alternative supplier and transferring know-how and other information relating to the Manufacture of the Drug Substance to Pfizer or such alternative supplier. [***] Protalix shall provide such assistance in accordance with a written transition plan (the "Manufacturing Transition Plan") that details the actions and timelines for transitioning the Manufacture of the Drug Substance to Pfizer or such alternative supplier in a timely and efficient manner without material risk or disruption to either Protalix or Pfizer and no later than the end of the Term (if in connection with the expiration or termination of the Agreement) or no later than the time agreed to by the parties (if in connection with Pfizer's exercise of its right to Manufacture or have a Third Party Manufacture the Drug Substance). Protalix shall provide the proposed Manufacturing Transition Plan to Pfizer for Pfizer's written approval, which shall not be unreasonably withheld, within [***] following Pfizer's request. In addition, upon Pfizer's request, Protalix shall use Commercially Reasonable Efforts to cause the counterparty to any contract relating to the Manufacture of the Drug Substance (a) to consent to the partial assignment to Pfizer or such alternative supplier of those rights necessary for such manufacture by Pfizer or such alternative supplier or (b) to otherwise reasonably cooperate with Pfizer in Pfizer's efforts to establish a new contractual relationship with such counterparty on substantially the same terms as the terms of its contract with Protalix.

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

SECTION 6. FINANCIAL PROVISIONS

6.1 Second Amendment Effective Date Payment. Within thirty (30) days following the Second Amendment Effective Date, Pfizer shall pay to Protalix the amount of thirty-six million dollars (US $36,000,000) (the "Pfizer Payment") in accordance with Section 7.2(a).

6.2 Deferred Payment. Within thirty (30) days of the fifth (5th) anniversary of the Second Amendment Effective Date, Protalix shall pay to Pfizer the non-refundable, non-creditable amount of four million three hundred thousand seven hundred sixteen dollars and forty-six cents (US $4,300,716.46) (the "Protalix Payment") in accordance with Section 7.2(b) and as set forth in the promissory note delivered by Protalix to Pfizer. Protalix shall have delivered a promissory note in the form of Exhibit H on the Second Amendment Effective Date (the "Promissory Note").

6.3 Payments With Respect to Commercialization in Israel. During the Israel Transition Period, [***]

6.4 Payments With Respect to Commercialization in Brazil. Until such time that Protalix has provided written notice to Pfizer permitting Pfizer to cancel its Brazilian marketing authorization with respect to the Licensed Product, [***]

6.5 Release of Payment Obligations. Upon (i) the payment by Pfizer to Protalix of the Pfizer Payment, Pfizer shall be deemed to have fully satisfied and discharged, and Protalix hereby fully and forever releases Pfizer and its Affiliates from, all payment obligations under Section 6 of the Amended Agreement that have accrued as of the Second Amendment Effective Date, including milestone payments and profit sharing payments, and (ii) the later to occur of (A) the delivery of the promissory note for the Protalix Payment by Protalix to Pfizer as required under Section 6.2 and (B) Protalix providing Pfizer with written notice permitting Pfizer to cancel its Brazilian marketing authorization with respect to the Licensed Product, Protalix shall be deemed to have fully satisfied and discharged, and Pfizer hereby fully and forever releases Protalix and its Affiliates from, all payment obligations under Section 2 of the First Amendment (which, for the avoidance of doubt, shall no longer be in effect as of the Second Amendment Effective Date) and Section 6 of the Amended Agreement that have accrued as of the Second Amendment Effective Date (except to the extent such payments under Section 2 of the First Amendment are payable pursuant to Section 6.4 of this Agreement) (collectively, the "Released Obligations"), other than payment of the Protalix Payment in accordance herewith. In addition, the Released Obligations include all associated reporting obligations, reconciliation payments and procedures and payments in respect of reimbursable expenses that may have accrued under Section 7 of the Amended Agreement. In connection with the foregoing release, each party hereby waives any and all rights to inspect or audit the books and records of the other party and its Affiliates and sublicensees relating to the Released Obligations and to seek any adjustment or modification of any amounts paid or payable in connection with any such audit or inspection.

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

SECTION 7. ACCOUNTING AND PROCEDURES FOR PAYMENT

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

7.2 Method of Payments.

(a) Each payment to be made hereunder by Pfizer to Protalix 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 Protalix's election, to the account designated on Appendix 7.2(a). With respect to any payment invoiced by Protalix to Pfizer, Protalix may designate a different bank account on such invoice. With respect to any other payment, Protalix may designate a different bank account at least forty-five (45) days before such payment is due.

(b) Each payment to be made hereunder by Protalix to Pfizer 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 Pfizer's election, to the account designated on Appendix 7.2(b), or to such other bank account as Pfizer shall designate in a notice at least fifteen (15) Business Days before the payment is due.

7.3 Tax Matters.

(a) VAT. It is understood and agreed between the parties that any payments made by Pfizer under this Agreement are inclusive of any value added or similar tax imposed upon such payments. It is understood and agreed between the parties that any payments made by Protalix to Pfizer under this Agreement are exclusive of any value added or similar tax (VAT), which shall be added thereon as applicable.

(b) Tax Cooperation.

(i) Subject to Section 7.3(c) to the extent Pfizer is required to deduct and withhold taxes on any payments to Protalix, Pfizer shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Protalix an official tax certificate or other evidence of such withholding sufficient to enable Protalix to claim credits for such payments of taxes. Protalix shall provide to Pfizer any tax forms that may be reasonably necessary in order for Pfizer not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Protalix shall use reasonable efforts to provide any such tax forms to Pfizer at least thirty (30) days prior to the due date for any payments for which Protalix desires that Pfizer apply a reduced withholding rate. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by law, of withholding taxes, 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. 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 Pfizer to Protalix under this Agreement.

(ii) Subject to Section 7.3(c), to the extent Protalix is required to deduct and withhold taxes on any payments to Pfizer, Protalix shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Pfizer an official tax certificate or other evidence of such withholding sufficient to enable Pfizer to claim credits for such payments of taxes. Pfizer shall provide to Protalix any tax forms that may be reasonably necessary in order for Protalix not to withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Pfizer shall use reasonable efforts to provide any such tax forms to Protalix at least thirty (30) days prior to the due date for any payments for which Pfizer desires that Protalix apply a reduced withholding rate. Each party shall provide the other with reasonable assistance to enable the recovery, as permitted by Law, of withholding taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the party bearing such withholding tax. Each party further agrees to provide reasonable cooperation to the other party, at the other party's expense, in connection with any official or unofficial tax audit or contest relating to payments made by Protalix to Pfizer under this Agreement.

(c) [***]

SECTION 8. PATENTS AND INFRINGEMENT

8.1 Filing and Prosecution. Protalix shall have the exclusive right, subject to Sections 8.2 through 8.5, to:

(a) file Patent Applications on any invention included in the Protalix Patent Rights;

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

(c) respond to oppositions, interferences, nullity actions, re-examinations, revocation actions and similar proceedings filed by Third Parties against the grant of Patents for such Patent Applications; and

(d) 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 and regulations of the particular Country in which the patent was granted.

(e) [***] shall be responsible for bearing [***] of the expenses and costs incurred by [***] in connection with the exercise of its rights under this Section 8.1.

8.2 Correspondence. [***] will keep [***] fully-informed of the status of the [***] Patent Rights to the extent the Protalix Patent Rights [***], and will provide [***] with copies of all substantive documentation submitted to, or received from, the patent offices in connection therewith. With respect to any substantive submissions that [***] is required to or otherwise intends to submit to a patent office regarding such Protalix Patent Rights, [***] shall use

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

Commercially Reasonable Efforts to provide a draft of such submission to [***] at least thirty (30) days prior to the deadline or intended filing date, whichever is earlier, for submission of such documentation. [***] shall have the right to review and comment upon any such submission by [***] to a patent office that could affect the scope of coverage or validity of any claim of the Protalix Patent Rights to the extent covering the Compound or Licensed Product, or the Development, Manufacture, or Commercialization of [***], and will provide such comments, if any, no later than ten (10) days prior to the applicable deadline or intended filing date. Notwithstanding the foregoing, when such substantive documentation submitted to or received from the patent offices is solely related to [***], [***] shall have the right, but no obligation, to fully inform [***] of the status of these Protalix Patent Rights.

(a) Upon [***] written request, provided that [***] submits such written request reasonably in advance of any relevant filing deadline or intended filing date, [***] will file Patent Applications directed to the rights licensed to [***] under this Agreement [***]

(b) With respect to Protalix Patent Rights that are [***][***] shall consider in good faith all comments provided by [***] with respect to a Protalix Patent Right to the extent relating to [***], and incorporate all such comments that [***] deems reasonable and appropriate. If [***] disagrees with any such comment provided by [***] after giving such comments due consideration, [***] shall provide [***] with an explanation of the basis for such disagreement. If a failure to incorporate [***]'s comment would reasonably be expected to impair the Licensed Product in the Field in the Territory, [***] shall have final-decision making authority with respect to filings and prosecution of such Protalix Patent Rights (other than the Protalix System Patent Rights). [***] shall have final-decision making authority with respect to filings and prosecution of Protalix Patent Rights relating solely to an [***] and with respect to filings and prosecution of Protalix Patent Rights that [***]

(c) Notwithstanding the foregoing, [***]'s obligation to keep [***] informed of the status of the Protalix System Patent Rights will be limited to situations where changes to the status of the Protalix System Patent Rights would reasonably be expected to impair the Licensed Product in the Field in the Territory. With respect to the Protalix System Patent Rights, [***] shall reasonably consider all comments provided by [***], but [***] shall have final-decision making authority with respect to filings and prosecution of the Protalix System Patent Rights.

8.3 Maintenance. Protalix will maintain for the full life thereof all Patent Rights under the Protalix Patent Rights where the abandonment for non-payment would [***]. Protalix will notify Pfizer of any decision (a) not to file applications for, or (b) not to enter the national phase for a PCT patent application (or not to validate a patent in a particular Country) for, or (c) to cease prosecution and/or maintenance of, or (d) not to pursue, or (e) to cease to pay the expenses of prosecution or maintenance of, any Protalix Patent Rights in any Country in the Territory. Protalix will provide such notice upon the earlier of (i) its decision with respect to any of the foregoing, or (ii) ninety (90) days prior to any filing or payment due date, or any other due date that requires action, in connection with such Protalix Patent Rights. In such event, Pfizer shall have the right to make the filing, or to continue the prosecution and maintenance of such

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

Patent Rights (other than Protalix System Patent Rights) in its own name and at its sole expense, and such Patent Rights shall be assigned to Pfizer and shall no longer be part of the Protalix Patent Rights. Notwithstanding the foregoing, Protalix shall have no obligation to provide such notice where the subject Protalix Patent Rights are directed solely to an [***].

8.4 Notices and Encumbrances. Protalix agrees that it will, and will cause its Affiliates to, (a) execute and file those notices and other filings as Pfizer shall request be made, from time to time with the United States Patent and Trademark Office (or any successor agency) or any analogous patent office in the Territory with respect to the rights granted under this Agreement and, (b) maintain (subject to Section 8.3) at all times during the Term sole ownership of the Patents and Patent Applications under the Protalix Patent Rights (other than Protalix Patent Rights directed solely to [***]), free and clear of any and all mortgages, liens, pledges, security interests, charges or encumbrances. Protalix shall also keep the Protalix Technology (other than Protalix Technology directed solely to or solely embodied in [***]), free and clear of any and all mortgages, liens, pledges, security interests, charges or encumbrances during the Term. For the sake of clarity, encumbrances as contemplated in this Section 8.4 specifically exclude licenses to Protalix Patent Rights and Protalix Technology, wherein such licenses are [***] [***] [***].

8.5 Patent Term Extensions. Pfizer shall have the first right, but not the obligation, to seek, in Protalix's name if so required, patent term extensions, and supplemental protection certificates and the like available under Law, including 35 U.S.C. § 156 and applicable foreign counterparts, in any Country in the Territory in relation to the Protalix Patent Rights covering the Compound (other than Protalix Patent Rights directed solely to the Compound [***]) or Licensed Products. In the event that Pfizer decides not to seek such patent term extension or supplemental patent protection in any Country in the Territory, Protalix shall have the right to seek such patent term extension or supplemental patent protection in any such Country. Protalix and Pfizer shall cooperate in connection with all such activities, and Pfizer, its agents and attorneys will give due consideration to all suggestions and comments of Protalix regarding any such activities, but in the event of a disagreement between the parties, as it relates to the Compound ([***]) or Licensed Product, Pfizer will have the final decision-making authority. Any costs incurred by Pfizer in connection with this Section 8.5 shall be borne [***]. Any costs incurred by Protalix in connection with this Section 8.5 shall be borne [***].

8.6 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) Pfizer 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 the Territory (other than Protalix Patent Rights directly solely to [***]), where such Third Party infringement would reasonably be expected [***]. In order to establish standing, Protalix, upon request of

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

Pfizer, agrees to timely commence or to join in any such litigation, at [***] and in any event to cooperate with Pfizer at [***]. Any costs and expenses incurred by Pfizer with respect to any such litigation or remedial measures shall be [***] and any recoveries resulting from such litigation or measures relating to a claim of a Third Party infringement in pursuing such claim, will be [***].

(ii) 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 occurring [***] and with respect to Third Party infringement of any Protalix Patent Rights directed solely to [***] and any such litigation or remedial measures shall be [***]. Protalix shall retain [***] received by Protalix as a result of its enforcement of Protalix Patent Rights under this Section 8.6(a)(ii).

(b) Infringement of Protalix Patent Rights [***]. Protalix shall have the sole right, but not the obligation, to institute litigation or take other remedial measures in connection with Third Party infringement occurring [***] and any such litigation or remedial measures shall be [***]. Protalix shall either (i) provide Pfizer with prior written notice of Protalix's intent to initiate a suit, take other appropriate action, or to not file suit or seek other redress or (ii) convene a meeting of the parties to discuss what would be in the parties' best interest with respect to the Third Party infringement occurring [***]. Protalix shall retain [***] received by Protalix as a result of its enforcement of Protalix Patent Rights under this Section 8.6(b).

8.7 Paragraph IV Notices.

(a) If either party receives a notice under 21 U.S.C. §355(b)(2)(A)(iv) or 355(j)(2)(A)(vii)(IV) directed to a Compound ([***]) or Licensed Product, concerning any Protalix Patent Right ("Paragraph IV Notice"), then it shall provide a copy of such notice to the other party promptly and in any event no later than two (2) Business Days after its receipt thereof. Pfizer shall have the exclusive right, but not the obligation, to initiate patent infringement litigation based on a Paragraph IV Notice directed to a Compound ([***]) or Licensed Product, concerning a Protalix Patent Right, and any expenses incurred by Pfizer with respect to such infringement litigation shall be [***]. Upon request of Pfizer, Protalix agrees to timely join as party−plaintiff in any such litigation, and in any event to cooperate with Pfizer in connection with such infringement action, including timely filing such action in Protalix's name if required. Pfizer shall promptly notify Protalix of its intention not to initiate patent infringement litigation based on such Paragraph IV Notice. The amount of any recovery from any such infringement suit with respect to activities in the Field in the Territory will be [***].

(b) Protalix and Pfizer are aware of currently proposed legislation in the United States that may create or affect the regulatory pathway for a follow-on biologic product to the Licensed Product. [***] To the extent required to establish standing, and possibly to comply with heretofore unknown regulations accompanying this regulatory pathway, [***], shall reasonably cooperate with [***] in any litigation or administrative action at [***] expense and shall commence or join in any such litigation or administrative action at [***] request and

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

expense. The amount of any recovery from any such proceedings shall first be used to pay reasonable costs, including attorneys' fees and the remaining amount of the recovery will be [***].

8.8 Other Actions by a Third Party. Each party shall promptly notify the other in the event of any (a) claims by a Third Party of alleged patent infringement by Pfizer or Protalix or any of their respective Affiliates with respect to [***] of a Compound ([***]) or Licensed Product or (b) legal or administrative action by any Third Party involving a Protalix Patent Right (other than Protalix Patent Rights directed solely to [***]) of which it becomes aware, including any nullity, revocation, reexamination or compulsory license proceeding. Pfizer shall have the first right, but no obligation, to defend against any such action involving such Protalix Patent Right in the Territory when the alleged patent infringement would reasonably be expected to [***], and any such defense shall be [***]. Protalix, upon request of Pfizer, agrees to join in any such action [***] and in any event to cooperate with Pfizer [***] If Pfizer fails to defend Protalix against any such action involving a Protalix Patent Right, then Protalix shall have the right to defend such action, and any such defense shall be[***]. Pfizer, upon request of Protalix, shall reasonably cooperate with Protalix in any such action [***].

8.9 Compensation to Inventors. [***]

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

8.11 In-Licensed Patents. With respect to this Section 8, "Protalix Patent Rights" shall include Patent Rights that are Controlled by Protalix or any of its Affiliates pursuant to a Third Party License (*i.e.,* such Patent Rights are not owned by Protalix or any of its Affiliates) only if [***]

SECTION 9. CONFIDENTIALITY; PUBLICATION

9.1 Confidential Information.

(a) Pfizer and Protalix each agree that during the Term and for five (5) years after the Term, it will keep confidential, and will cause its Affiliates to keep confidential, all of the other party's Confidential Information that is disclosed to it, or to any of its Affiliates. Pfizer and Protalix each agree to take such action, and to cause its Affiliates to take such action, to preserve the confidentiality of Protalix Confidential Information and Pfizer Confidential Information, respectively, as it would customarily take to preserve the confidentiality of its own similar types of confidential information.

(b) Each of Pfizer, Protalix and their respective Affiliates agree (i) to use Protalix Confidential Information and Pfizer Confidential Information, respectively, only as expressly permitted in this Agreement and (ii) not to disclose Protalix Confidential Information

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

and Pfizer Confidential Information, respectively, to any Third Parties under any circumstance without the prior consent of the other party, except as expressly permitted in this Agreement.

9.2 Permitted Disclosure of Confidential Information.

(a) Disclosure of Protalix Confidential Information.

(i) Notwithstanding anything to the contrary in this Section 9, Pfizer may disclose Protalix Confidential Information: (A) to Governmental Authorities (x) to the extent desirable to obtain or maintain Regulatory Approvals for the Compound or Licensed Product within the Territory, and (y) in order to respond to inquiries, requests or investigations relating to this Agreement; (B) to Sublicensees, outside consultants, contractors, advisory boards, managed care organizations, and non-clinical and clinical investigators, in each case to the extent desirable to Develop, register or Commercialize the Compound or Licensed Product; provided that Pfizer shall obtain the same confidentiality obligations and degree of care from such Third Parties as it obtains with respect to its own similar types of confidential information; provided further that no Protalix Confidential Information consisting of non-public information relating to Protalix's manufacturing know-how may be disclosed (and, notwithstanding anything to the contrary herein, Protalix shall not have any obligation under this Agreement to disclose any such manufacturing know-how) to any Sublicensee that is a direct competitor of Protalix in the field of plant cell expressed biologics manufacturing, except to the extent such disclosure is necessary for Pfizer to identify and establish an alternative source of supply of Drug Substance pursuant to Section 5.21(d); (C) in connection with filing or prosecuting Patent Rights or trademark rights as permitted by this Agreement; (D) in connection with prosecuting or defending litigation as permitted by this Agreement; (E) in connection with or included in scientific presentations and publications relating to the Compound or Licensed Product, including abstracts, posters, journal articles and the like, and posting results of and other information about clinical trials to clinicaltrials.gov or PhRMA websites; and (F) to the extent necessary or desirable in order to enforce its rights under this Agreement.

(ii) If Pfizer is required or requested to disclose Protalix Confidential Information (x) as required by Law or legal proceedings or (y) as required to be contained in Pfizer's financial statements prepared in accordance with GAAP, as applied on a consistent basis, Pfizer shall (1) with respect to disclosures described in clause (x), use Commercially Reasonable Efforts to obtain confidential treatment of financial and trade secret information, and (2) with respect to disclosures described in clauses (x) and (y), if reasonably practicable under the circumstances, give Protalix sufficient advance notice of the text so that Protalix will have the opportunity to seek, at its own cost, an appropriate protective order or other remedy or waive compliance with the provisions of this Agreement. If Protalix seeks a protective order, Pfizer will cooperate. If Protalix fails to obtain a protective order or waive compliance with the relevant portions of this Agreement, Pfizer will disclose only that portion of information concerning the Compound or Licensed Product which its legal counsel determines it is required to disclose.

(b) Disclosure of Pfizer Confidential Information.

(i) Notwithstanding anything to the contrary in this Section 9, Protalix may disclose Pfizer Confidential Information to: (x) Governmental Authorities in order to respond to inquiries, requests or investigations relating to this Agreement or to comply with applicable Laws and (y) to the extent necessary or desirable in order to enforce its rights under this Agreement.

(ii) If Protalix is required or requested to disclose Pfizer Confidential Information (x) as required by Law or legal proceedings or in connection with Section 9.2(b)(i) above or (y) as required to be contained in Protalix financial statements prepared in accordance with GAAP, as applied on a consistent basis, Protalix shall (1) with respect to disclosures described in clause (x), use Commercially Reasonable Efforts to obtain confidential treatment of financial and trade secret information, and (2) with respect to disclosures described in clauses (x) and (y), if reasonably practicable under the circumstances, give Pfizer sufficient advance notice of the text so that Pfizer will have the opportunity to seek, at its own cost, an appropriate protective order or other remedy or waive compliance with the provisions of this Agreement. If Pfizer seeks a protective order, Protalix will cooperate. If Pfizer fails to obtain a protective order or waive compliance with the relevant portions of this Agreement, Protalix will disclose only that portion of information concerning the Compound or Licensed Product which its legal counsel determines it is required to disclose.

(iii) If Protalix desires to disclose Pfizer Confidential Information that (x) has been announced previously in accordance with Section 9.4 (Publicity), or (y) has been announced previously by Pfizer, such disclosure is permitted so long as (1) it is consistent with such previously announced statement and (2) Pfizer is permitted a review and comment period of no fewer than sixty (60) days prior to the planned disclosure to redact any Pfizer Confidential Information and ensure the disclosure is within the scope of previous disclosures as set forth in this Section 9.2(b)(iii).

9.3 Publication.

(a) Subject to Section 9.3(d), neither Pfizer nor any of its Affiliates or their respective employees, consultants, contractors and agents shall publish or present any information, including the results of any preclinical or clinical studies, with respect to the Compound or Licensed Product unless Pfizer has used Commercially Reasonable Efforts to provide Protalix with thirty (30) days' notice prior to any such publication or presentation.

(b) Subject to Section 9.3(c) and Section 9.3(d), neither Protalix nor any of its Affiliates or their respective employees, consultants, contractors, licensees and agents shall publish or present any information, including the results of any preclinical or clinical studies, with respect to the Compound ([***]) or Licensed Product without the prior written approval of Pfizer ([***]), except as may be required by Law or legal proceedings.

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

(c) Section 9.3(a) does not prohibit: (i) 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 that does not contain information with respect to the Compound (other than the Oral Formulation) or Licensed Product; (ii) Protalix and its Affiliates (and their respective employees, consultants, contractors, licensees and agents) from publishing or presenting information relating to the Oral Formulation; or (iii) Protalix and its Affiliates (and their respective employees, consultants, contractors, licensees and agents) from publishing or presenting information that has been either previously published or presented by Protalix in accordance with Section 9.3(a) or by Pfizer. Protalix will use Commercially Reasonable Efforts to provide Pfizer a copy of any such proposed publication or presentation described in clauses (i) or (ii) of this Section 9.3(c) at least thirty (30) days prior to any such publication or presentation.

(d) Nothing in this Section 9.3 shall be construed to (a) limit the rights of either party's Third Party clinical investigators to publish the results of their studies or (b) prevent either party from complying with applicable Law with respect to the disclosure of clinical study data and results or of any other material matter or information.

9.4 Publicity.

(a) The public announcement of the execution of this Agreement is set forth on Exhibit I attached hereto and shall be promptly disseminated as a press release following the execution of this Agreement by Protalix.

(b) Except as set forth in Sections 9.3, 9.4(a) or 9.4(c) or with respect to any activities or contemplated activities by Protalix outside of the Territory, Protalix shall not make (and shall cause its Affiliates not to make) any public statement (written or oral), including in analyst meetings, concerning the terms of, or events related to, this Agreement or concerning the Licensed Product in the Territory without the prior written approval of Pfizer (which may be withheld in its sole and final discretion) except where such statement: (i) is required by Law or legal proceedings (or to respond to a specific request of the securities exchange upon which Protalix's securities are listed); (ii) is required to be contained in Protalix financial statements prepared in accordance with GAAP; (iii) has been announced previously in accordance with this Section 9.4; or (iv) has been announced previously by Pfizer; so long as, in the case of (iii) or (iv), such public statement is consistent with such previously announced statement. In the case of any public statement (written or oral) that is required by Law or legal proceedings, Protalix shall (and shall cause its Affiliates to) (x) use Commercially Reasonable Efforts to obtain confidential treatment of financial and trade secret information (except in connection with press releases) and (y) if reasonably practicable under the circumstances, give Pfizer sufficient advance notice of the text so that Pfizer will have the opportunity to comment upon the statement, and give due consideration to any specific reasonable comments of Pfizer on such text timely received from Pfizer.

(c) Section 9.4(b) does not prohibit Protalix from making public announcements that any of the following has commenced or has been completed: any [***];

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

provided that such public announcement complies with all applicable Laws. Protalix will provide Pfizer a copy of any such proposed public announcement at least ten (10) Business Days prior to such announcement so that Pfizer will have the opportunity to comment upon the announcement, and give due consideration to any specific reasonable comments of Pfizer on such text timely received from Pfizer. For the avoidance of doubt, this Section 9.4(c) shall be subject to Section 9.3(b).

9.5 Filing, Registration or Notification of the Agreement. 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 provide to the other party a redacted version of this Agreement indicating the sections of the Agreement to be redacted in such filing and both parties shall agree in good faith upon a final redacted version of the Agreement for such filing (the "Redacted Agreement"). The disclosing 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 ten (10) years, (c) permit the other party to review and approve such request for confidential treatment and any subsequent correspondence with respect thereto at least five (5) 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 for this Agreement, the Original Agreement and the First Amendment, and (vi) 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. Notwithstanding the foregoing or anything to the contrary herein, Pfizer acknowledges and agrees that Protalix BioTherapeutics, Inc. shall have the right to describe (and, as reasonably necessary, include) this Agreement in its U.S. Securities and Exchange Commission ("SEC") filings; provided, however, that Protalix shall give Pfizer sufficient advance notice of the text describing this Agreement in its filings with the SEC so that Pfizer will have the opportunity to comment upon such description, and Protalix shall give due consideration to any specific reasonable comments of Pfizer on such description timely received from Pfizer.

SECTION 10.REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 Protalix Representations, Warranties and Covenants. Protalix hereby represents and warrants as of the Second Amendment Effective Date (unless otherwise indicated) and covenants to Pfizer as follows:

(a) Protalix has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and

performance of this Agreement by Protalix have been duly and validly authorized and approved by proper corporate action on the part of Protalix, and Protalix has taken all other action required by Law, its certificate of incorporation, by-laws or other organizational documents or any agreement to which it is a party or to which it may be subject, required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of Pfizer, this Agreement constitutes a legal, valid and binding obligation of Protalix, enforceable against Protalix in accordance with its terms.

(b) The execution and delivery of this Agreement by Protalix and the performance by Protalix contemplated hereunder does not and will not violate any Laws (as in effect on the Second Amendment Effective Date), except for such violations that would not have an adverse effect on the ability of Protalix to perform its obligations under this Agreement, or any order of any court or Governmental Authority in effect on the Second Amendment Effective Date.

(c) To the knowledge of Protalix, the Protalix Patent Rights owned by Protalix or its Affiliates are valid and enforceable and no Third Party (i) is infringing any such Protalix Patent Rights or (ii) has challenged the validity or enforceability of the Protalix Patent Rights owned by Protalix or its Affiliates (including by way of example through the institution or written threat of institution of interference, nullity or similar invalidity proceedings before the United States Patent and Trademark Office or any analogous foreign entity).

(d) To the knowledge of Protalix, neither (i) the Manufacture, use or Development (including the use or provision of Licensed Product in Early Access Programs) by Protalix (or its Affiliates) of the Drug Substance or Licensed Product on or prior to the Second Amendment Effective Date has infringed nor (ii) the Manufacture, use, Development, sale, offer for sale, supply or importation by Protalix or Pfizer (or their respective Affiliates) of the Drug Substance or Licensed Product (as currently constituted) on or prior to the Second Amendment Effective Date or as contemplated by this Agreement has infringed or would infringe any issued Patent of any Third Party that exists on the Second Amendment Effective Date or, if and when issued, any valid claim within any Third Party Patent Application published before the Second Amendment Effective Date.

(e) Exhibit B contains a complete and correct list as of the Second Amendment Effective Date of all Patents and Patent Applications owned by or otherwise Controlled by Protalix (and indicating which entity owns or Controls each Patent and Patent Application and which are owned and which are Controlled) covering the Compound, any Licensed Product and the System.

(f) Protalix is the sole and exclusive owner of all the Protalix Patent Rights and Protalix Technology (other than Patent Rights licensed to Protalix as described in Exhibit B), free of any lien, encumbrance, charge, security interest, mortgage or other similar restriction, and no Person (including any Affiliate of Protalix) has any right, interest or claim in or to, and neither Protalix nor any of its Affiliates has entered into any agreement granting any right, interest or claim in or to any Protalix Patent Rights owned by Protalix or its Affiliates or Protalix Technology to any Third Party, including any academic organization or agency.

(g) Protalix has complied in all material respects with all applicable Laws, including any disclosure requirements, in connection with the filing, prosecution and maintenance of the Protalix Patent Rights (other than Patent Rights licensed to Protalix) in the Territory.

(h) Prior to the Second Amendment Effective Date, to the extent such activities have been conducted by Protalix, its Affiliates or Third Parties acting on behalf of Protalix, the Compound, Drug Substance and Licensed Product have been Developed, Manufactured, stored, labeled, distributed and tested by Protalix and its Affiliates and, to the knowledge of Protalix, by any Third Parties acting on behalf of Protalix, in compliance in all material respects with all applicable Laws.

(i) Other than Patent Rights licensed to Protalix as described in Exhibit B, none of the rights of Protalix or its Affiliates under the Protalix Patent Rights were developed with federal funding from the United States government or any other Governmental Authority, other than grants received by Protalix from the Office of the Chief Scientist of the Israeli Ministry of Industry, Trade and Labor (the "Israel Grant"), a copy of which Protalix has provided to Pfizer prior to the Second Amendment Effective Date. No obligations, restrictions or covenants have been imposed upon Protalix or its licensees, the Drug Substance or the Licensed Product in connection with the Israel Grant.

(j) Protalix has obtained assignments from the inventors of all inventorship rights relating to the Protalix Patent Rights (other than Patent Rights licensed to Protalix), and all such assignments of inventorship rights covering the Protalix Patent Rights (other than Patent Rights licensed to Protalix) are valid and enforceable.

(k) Each Third Party License as heretofore delivered by Protalix to Pfizer represents the complete agreement and understanding between the Third Party licensor(s) under such Third Party License and Protalix relating to the Protalix Patent Rights and Protalix Technology which are the subject of such Third Party License. No Third Party License has been modified, supplemented or amended, other than by amendments thereto provided to Pfizer prior to the Second Amendment Effective Date. Except for the Third Party Licenses listed on Exhibit C, there are no agreements to which Protalix or any of its Affiliates is a party pursuant to which Protalix or any of its Affiliates has a license, or an option to obtain a license, or holds an immunity from suit, with respect to patents which (i) are pending, applied for, granted or registered, and (ii) but for Protalix's rights under such agreements, could be asserted by Third Parties to be infringed by the Manufacture, distribution, use, marketing or sale of the Drug Substance or Licensed Product. Each Third Party License is in full force and effect, all payments to date required to be made thereunder by Protalix have been made, and Protalix is in compliance in all respects with its respective obligations thereunder. [***]

(l) Protalix has previously delivered to Pfizer all of its material agreements with any Third Parties regarding the Development, supply and Manufacture of all goods and services relating to the Drug Substance and Licensed Product to the extent requested by Pfizer, none of which have been modified, supplemented or amended in any material respect, other than

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

by amendments thereto provided to Pfizer prior to the Second Amendment Effective Date. Each such agreement is in full force and effect, all payments to date required to be made thereunder by Protalix have been made, and Protalix is in compliance in all respects with its respective obligations thereunder.

(m) Protalix has heretofore disclosed to Pfizer all material scientific and technical information and all material information relating to safety and efficacy known to it or its Affiliates with respect to the Drug Substance and Licensed Product.

(n) Protalix has heretofore disclosed to Pfizer all material correspondence and contact information between Protalix and the FDA and any other Governmental Authorities regarding the Drug Substance or Licensed Product.

(o) Neither the execution and delivery of this Agreement nor the performance hereof by Protalix requires Protalix to obtain any permits, authorizations or consents from any Governmental Authority or from any other Person, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination, rescission, renegotiation or acceleration under, or trigger any other rights under, any agreement or contract to which Protalix is a party or to which it may be subject that relates to the Protalix Patent Rights, Protalix Technology, Drug Substance or Licensed Product.

(p) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Protalix, threatened against Protalix, any of its Affiliates or any Third Party, in each case in connection with the Protalix Patent Rights owned by Protalix, Protalix Technology owned by Protalix, the Drug Substance, the Licensed Product, the System, Protalix's business practices relating to the Drug Substance or the Licensed Product, Protalix's compliance with the Foreign Corrupt Practices Act of 1977, as amended and the U.K. Bribery Act, or relating to the transactions contemplated by this Agreement.

(q) To the knowledge of Protalix, information provided by Protalix in response to any of Pfizer's due diligence requests prior to the Second Amendment Effective Date was in all material respects complete, truthful and accurate.

(r) Protalix and, to Protalix's knowledge, any agent or subcontractor of Protalix engaged in activities related to this Agreement has not and will not directly or indirectly offer or pay, or authorize such offer or payment, of any money or anything of value or improperly seek to influence any Government Official or any other person in order to gain an improper advantage, and has not accepted, and will not accept in the future such payment in connection with this Agreement. For purposes of this Section 10.1, a "Government Official" is defined as and includes: (i) any elected or appointed government official (e.g., a member of a ministry of health); (ii) any employee or person acting for or on behalf of a Government Official, agency, or enterprise performing a governmental function; (iii) any political party, officer, employee, or person acting for or on behalf of a political party or candidate for public office; (iv) an employee or person acting for or on behalf of a public international organization; or (v) any person otherwise categorized as a Government Official under local Law where "Government"

includes all levels and subdivisions of non-U.S. governments (i.e., local, regional, or national and administrative, legislative, or executive).

(s) To the knowledge of Protalix, all information provided by Protalix or its Affiliate to Pfizer during pre-contractual due diligence, including the information provided in the compliance questionnaire (the "Compliance Questionnaire"), is in all material respects complete, truthful and accurate. Further, Protalix undertakes to promptly update this representation and warranty if (during the Term) Protalix, or any of its employees, or individuals, or subcontractors who will be primarily responsible for performing under this Agreement, or a relative of such an employee or individual or subcontractor, becomes a Government Official or, if a government or Government Official becomes an owner of five percent (5%) or more of Protalix.

(t) Protalix will comply in all material respects with Pfizer's Anti-Bribery and Anti-Corruption Principles set forth on Appendix 10.1(t).

(u) Protalix will complete and submit to Pfizer an executed copy of the compliance certification attached hereto as Exhibit K on the Second Amendment Effective Date.

(v) [***]

(w) Protalix has implemented, and will maintain, a system of internal accounting controls designed to ensure the making and keeping of fair and accurate books, records, and accounts with respect to Protalix's business or any services provided under the Agreement, as and to the extent required under Section 4.8 and Section 5.15 hereof.

(x) Protalix undertakes to promptly inform Pfizer if it becomes aware of any compliance issues related to any allegations of improper payments to healthcare professionals or Government Officials that have not been previously reported and related to any discussions, notices or changes with respect to any investigation by Governmental Authorities or Regulatory Authorities or prosecution involving allegations of corruption or serious criminal misconduct involving its business.

(y) Protalix will, subject to and in accordance with Section 5.15 hereof, permit, during the Supply Term and for [***] after final payment has been made under the Agreement, Pfizer's internal and external auditors access to any relevant books, documents, papers, and records of Protalix involving transactions related to the Agreement.

(z) With respect to the Commercialization of the Licensed Product in Israel, since January 1, 2015, Protalix has not (i) materially altered its activities and practices with respect to inventory levels of the Licensed Product maintained at the wholesale, pharmacy or institutional levels, including its practices with respect to product samples, or (ii) sold, transferred or given any supplies or samples of the Licensed Product to any Third Party in or for use in Israel, in each case, except in the ordinary course of business that is consistent with past practice.

(aa) [***]

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

10.2 Manufacturing Representations, Warranties and Covenants. Each party hereby represents and warrants as of the Second Amendment Effective Date (unless otherwise stated) and covenants to the other party as follows:

(a) All Drug Substance and Licensed Product Manufactured and supplied hereunder by, or under authority of, such party shall be Manufactured and supplied such that:

(i) Any Facility and all equipment, tooling and molds utilized in the Manufacture and supply of Drug Substance and Licensed Product hereunder by such party shall, during the Term, be maintained in good operating condition and shall be maintained and operated in accordance with all applicable Laws. The Manufacturing and storage operations, procedures and processes utilized by such party in Manufacture and supply of Drug Substance and Licensed Product hereunder (including any Facility) shall be in full compliance with all applicable Laws, including GMP and health and safety Laws.

(ii) Such party shall perform all of its Manufacturing and supply obligations under this Agreement in full compliance with all applicable Laws. Such party shall hold during the Term all licenses, permits and similar authorizations required by any Governmental Authority for such party to perform its Manufacturing and supply obligations under this Agreement.

(b) The Drug Substance and Licensed Product, as applicable, furnished by such party [***]:

(i) shall be Manufactured, packaged, labeled, handled, stored and shipped in accordance with, shall be of the quality specified in, and shall conform to, the Product Specifications;

(ii) shall be Manufactured, packaged, labeled, handled, stored and shipped in compliance with all applicable Laws including GMP, and in accordance with the Quality Agreement (with respect to Drug Substance and/or Licensed Product furnished by Protalix to Pfizer under this Agreement) and any other quality assurance requirements provided in writing to such party by the other party, and this Agreement;

(iii) shall not contain any material that has not been used, handled or stored in accordance with the Product Specifications, all applicable Laws, the Quality Agreement (with respect to Drug Substance and/or Licensed Product furnished by Protalix to Pfizer under this Agreement) and any other quality assurance requirements of the other party or the supplier of such material, and this Agreement;

(iv) shall not contain any material that would cause the Drug Substance or Licensed Product to be adulterated or misbranded within the meaning of any Laws;

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

(v) shall be free from defects in material and workmanship; and

(vi) shall, at the time delivered, have a remaining shelf-life as specified in the Quality Agreement (with respect to Drug Substance and/or Licensed Product furnished by Protalix to Pfizer under this Agreement) and Section 5.8(a).

(c) Such party does not currently employ and will not employ during the Term, and such party does not use as a subcontractor and will not use during the Term, and such party's subcontractors do not currently employ and will not employ or engage during the Term, any Person that has been debarred or is subject to debarment or has otherwise been disqualified or suspended from performing scientific or clinical investigations or otherwise subjected to any restrictions or sanctions by the FDA or any other Governmental Authority or Regulatory Authority or professional body with respect to the performance of scientific or clinical investigations; any other Person who by virtue of any Laws is or may be disqualified, restricted or prevented in any way from performing the services to be provided under this Agreement; or any Person convicted of a criminal offense in relation to:

(i) In respect of a company, partnership or association, the development or approval, including the process for development or approval of an abbreviated drug application;

(ii) In respect of an individual:

(A) the development or approval of any drug product or otherwise relating to the regulation of any drug product; or

(B) bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail, extortion, falsification or destruction of records or interference with, obstruction of an investigation into a prosecution of any criminal offense.

(d) Notwithstanding the foregoing in this Section 10.2, Pfizer shall not be responsible for any failure to conform to the representations and warranties under Sections 10.2(a) and 10.2(b), and shall have no liability to Protalix with respect thereto to the extent that Pfizer's failure to conform to such representations and warranties is as a result of an act or omission of Protalix, Protalix's Affiliates or their respective agents, consultants or contractors in respect of the Manufacture of Drug Substance. Notwithstanding the foregoing in this Section 10.2, Protalix shall not be responsible for any failure to conform to the representations and warranties under Sections 10.2(a) and 10.2(b), and shall have no liability to Pfizer with respect thereto to the extent that Protalix's failure to conform to such representations and warranties is as a result of an act or omission of Pfizer, Pfizer's Affiliates or their respective agents, consultants or contractors in respect of their Fill/Finish activities or supply of Licensed Product to Protalix for Commercialization in Israel or in respect of the Drug Substance after acceptance by Pfizer of the Drug Substance supplied to Pfizer, such as a failure to properly store the Drug Substance.

10.3 Environmental Representations, Warranties and Covenants. Each party hereby represents and warrants as of the Second Amendment Effective Date (unless otherwise indicated) and covenants to the other party as follows:

(a) Compliance With Environmental Laws.

(i) To the knowledge of such party, there is no pending or threatened governmental enforcement action or private claim against such party pursuant to applicable Environmental Law, no Release or threatened Release of Hazardous Materials, nor any other existing environmental conditions, events or circumstances that are reasonably likely to limit, impede or otherwise jeopardize such party's ability to meet its Manufacturing obligations under this Agreement.

(ii) Such party shall perform all of the Manufacturing services to be provided by it hereunder in compliance with all Environmental Laws and all licenses, registrations, notifications, certificates, approvals, authorizations or permits required under applicable Environmental Laws ("Environmental Permits"), except where such non-compliance would not be reasonably likely to limit, impede or otherwise jeopardize such party's ability to meet its Manufacturing obligations under this Agreement. Such party shall abate any condition or practice, regardless of whether such condition or practice constitutes non-compliance with Environmental Laws, with respect to its usage, handling, storage or disposal of Hazardous Materials, that would be reasonably likely to limit, impede or otherwise jeopardize such party's ability to fulfill its Manufacturing obligations under this Agreement.

(b) Notice to Other Party. Such party shall provide the other party with reasonably prompt notice in the event of any significant event, occurrence or circumstance, including any governmental or private action in connection with such party's compliance with applicable Environmental Laws or with respect to such party's usage, handling, storage or disposal of Hazardous Materials, which would be reasonably likely to limit, impede or otherwise jeopardize such party's ability to fulfill its Manufacturing obligations under this Agreement. These could include, but are not limited to: (i) material revocation or modification of any of such party's Environmental Permits, (ii) any action by Governmental Authorities that may reasonably lead to the material revocation or modification of such party's Environmental Permits, (iii) any Third Party claim against the management or ownership of any Facility pursuant to applicable Environmental Law that could reasonably and materially impact such party's obligations under this Agreement, (iv) any fire, explosion, significant accident (one causing serious injury or fatality), or catastrophic Release of Hazardous Materials, (v) any significant non-compliance with Environmental Laws, and (vi) any environmental condition or operating practice that may reasonably be believed to present a significant threat to human health, safety or the environment.

(c) Equipment. Such party shall be solely responsible for the safe operation and maintenance of all equipment used to fulfill its Manufacturing obligations under this Agreement, and all associated employee training, regardless of whether the equipment is owned by such party, the other party or a Third Party.

(d) Environmental, Health and Safety Reviews. Each party shall permit the other party reasonable access to conduct periodic reviews during regular business hours of the environmental and health and safety practices and performance of the Facility(ies) where such party's performance is occurring. In connection with such audit or evaluation, such party shall assist in the other party's completion of an Environmental Health & Safety survey of such party or the scheduling of an Environmental Health & Safety audit of any Facility, as applicable. Such party will provide copies of all Environmental Permits to the other party upon request in connection with such review. The other party shall share its findings with such party as soon as practicable and such party shall correct, at no expense to the other party, such deficiencies in its environmental and health and safety management practices that materially jeopardize its ability to fulfill its Manufacturing obligations under this Agreement. Such party acknowledges that such reviews and evaluations conducted by the other party are for the benefit of the other party only; they are not a substitute for such party's own environmental and health and safety management obligations under this Agreement and accordingly, such party may not rely upon them.

10.4 Pfizer Representations, Warranties and Covenants. Pfizer hereby represents and warrants as of the Second Amendment Effective Date (unless otherwise indicated) and covenants to Protalix as follows:

(a) Pfizer has the corporate power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement by Pfizer have been duly and validly authorized and approved by proper corporate action on the part of Pfizer, and Pfizer has taken all other action required by Law, its certificate of incorporation or by-laws, or any agreement to which it is a party or to which it may be subject, required to authorize such execution, delivery and performance. Assuming due authorization, execution and delivery on the part of Protalix, this Agreement constitutes a legal, valid and binding obligation of Pfizer, enforceable against Pfizer in accordance with its terms.

(b) The execution and delivery of this Agreement by Pfizer and the performance by Pfizer contemplated hereunder does not and will not violate any Laws, except for such violations that would not have an adverse effect on the ability of Pfizer to perform its obligation under this Agreement, or any order of any court or Governmental Authority.

(c) Neither the execution and delivery of this Agreement nor the performance hereof by Pfizer requires Pfizer to obtain any permits, authorizations or consents from any Governmental Authority (other than any Regulatory Approvals relating to the Manufacture, use, importation or sale of the Compound or Licensed Product) or from any other Person, and such execution, delivery and performance will not result in the breach of or give rise to any right of termination under any agreement or contract to which Pfizer is a party or to which it may be subject, except for those breaches or rights that would not adversely affect the ability of Pfizer to perform its obligations under this Agreement.

(d) There is no action, claim, demand, suit, proceeding, arbitration, grievance, citation, summons, subpoena, inquiry or investigation of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to the knowledge of Pfizer, threatened against Pfizer

or any of its Affiliates or any Third Party relating to the transactions contemplated by this Agreement.

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

SECTION 11. ADDITIONAL COVENANTS

11.1 Restrictions on Transfers and Liens. Protalix shall not (and shall cause its Affiliates not to) sell, assign or otherwise transfer to any Person any Protalix Patent Rights or any Protalix Technology (or agree to do any of the foregoing), except to the extent permitted by, and in compliance with, Section 18.6 (including, for the avoidance of doubt, to any permitted assignee of the Agreement permitted by and in compliance with Section 18.6). In addition, Protalix hereby covenants and agrees that Protalix shall not incur or permit to exist (and shall cause each of its Affiliates not to incur or permit to exist), with respect to any Protalix Patent Rights owned by Protalix and/or Protalix Technology owned by Protalix, any lien, encumbrance, charge, security interest, mortgage, liability, grant of license to Third Parties in the Field in the Territory or other restriction (including in connection with any indebtedness). For purposes of clarity, this Section 11.1 is not intended to prohibit Protalix from (i) licensing to an Affiliate of Protalix or a Third Party rights under any Protalix Patent Rights or any Protalix Technology to the extent such rights have not been licensed to Pfizer pursuant to this Agreement and to the extent such license by Protalix does not otherwise conflict with the terms of this Agreement, or (ii) otherwise entering into any collaboration, license, assignment or other commercial agreement with a Third Party with respect to the Protalix Patents or Protalix Technology in relation to any products (excluding the Licensed Product) outside of the Field.

11.2 Third Party Licenses and Agreements. Protalix (a) shall not execute or otherwise permit, and shall cause its Affiliates to refrain from executing or otherwise permitting, any amendment, modification or waiver to any of the Third Party Licenses without the prior written consent of Pfizer, (b) shall not make any election or exercise any right or option (or omit to take any action) which would, and shall cause its Affiliates to refrain from making any election or exercising any right or option (or omitting to take any action) which would, terminate or relinquish in whole or in part any right under a Third Party License, (c) shall comply, and shall cause its Affiliates to comply in all respects, with all of its, and its Affiliates', obligations under the Third Party Licenses, (d) shall take, and shall cause its Affiliates to take, such actions as shall be necessary to keep in full force and effect the Third Party Licenses, and (e) shall give prompt notice to Pfizer, together with a detailed summary of outstanding issues if Pfizer so requests, of any notice received from the Third Party, of any actual or alleged defaults, breaches, violations, proposed amendments or proposed modifications of, or any proposed waivers under, any of the Third Party Licenses by any of the parties thereto. Protalix shall not assign or otherwise transfer

any Third Party License or any of its rights or obligations thereunder to any Person (or agree to do any of the foregoing) except to the extent permitted by, and in compliance with, Section 18.6. This Section 11.2 shall apply to the [***] to the same extent it applies to a Third Party License.

11.3 Compliance with Laws. Each of Protalix and Pfizer 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.

11.4 Coordination outside the Territory. Protalix and its Affiliates shall not, unless required by applicable Law, (a) conduct, or consent to or support any activities by a Third Party, with respect to the Licensed Product in the Field outside the Territory (including investigator-initiated research) if, in the good faith and reasonable judgment of Protalix, such activities would reasonably be expected to adversely impact the market for the Licensed Product in the Field in the Territory in any material respect, or (b) make any revisions to the labeling for the Licensed Product in the Field outside the Territory without first discussing such activities with Pfizer.

11.5 Protalix Non-Compete. From the Second Amendment Effective Date until the earlier of (a) the effective date of termination of this Agreement or (b) the [***] anniversary of the Second Amendment Effective Date, neither Protalix nor any of its Affiliates shall, directly or indirectly, alone or in collaboration with any Third Party, Commercialize in any Country in the Territory any Competing Product.

11.6 Limitation on Non-Compete Restrictions. Notwithstanding anything to the contrary herein, neither Protalix nor any of its Affiliates will be deemed to be in breach of the restrictions set forth in Section 11.5, if Protalix or any of its Affiliates undergoes [***] (and such Commercialization shall not be deemed to be a breach of Section 11.5).

11.7 [***]

11.8 [***]

11.9 [***]

SECTION 12.[RESERVED.]

SECTION 13.TERM

This Agreement shall be effective as of the Second Amendment Effective Date and shall remain in effect until the later of (i) the end of the term of the last to expire of the Protalix Patent Rights and (ii) the expiration of the Supply Term, unless earlier terminated pursuant to Section 14 (the "Term").

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

Section 14. TERMINATION

14.1 Pfizer Termination Right for Convenience. At any time and for any reason, Pfizer shall have the right, at Pfizer's sole discretion, to terminate this Agreement in its entirety, or with respect to a particular Country or Countries within the Territory, such termination to be effective upon thirty (30) days prior written notice to Protalix.

14.2 Pfizer Termination Right for Breach. If Protalix materially breaches or materially defaults in the performance or observance of any of its obligations under this Agreement related to the Manufacture of the Drug Substance (including a Failure to Supply) or a violation of any applicable anti-corruption law, and such breach or default is not cured within ninety (90) days after Pfizer provides Protalix with written notice specifying such breach or default, then, in addition to all other remedies available at law or in equity, Pfizer shall have the right to terminate this Agreement by providing Protalix written notice within ten (10) days following the expiration of such ninety (90)-day period (such termination to be effective upon receipt of such notice). For the avoidance of doubt, and notwithstanding the foregoing, a breach of Section 10.1(r) shall be considered a material breach for purposes of this Section 14.2.

14.3 Protalix Right of Termination. Protalix shall have no right to terminate this Agreement for any reason other than as set forth in this Section 14.3. If Pfizer materially breaches or materially defaults in the performance or observance of any of its obligations under this Agreement, and such breach or default is not cured within ninety (90) days after Protalix provides Pfizer with written notice specifying such breach or default, then Protalix shall have the right to terminate this Agreement by providing Protalix written notice within ten (10) days following the expiration of such ninety (90)-day period (such termination to be effective upon receipt). For purposes of this Section 14.3, material breaches or material defaults in the performance or observance of any of Pfizer's obligations under this Agreement (for which a termination right may be triggered if such breach is not cured as set forth above) shall be limited to: (i) Pfizer's failure to pay the Price for the Drug Substance in accordance with the terms of this Agreement and such failure to pay is not being disputed in good faith; and (ii) Pfizer's breach of Section 3.7.

14.4 Continuing and Accrued Obligations and Surviving Provisions. 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 any payment from Pfizer that accrued in accordance with this Agreement prior to the effective date of such termination, including for any Drug Substance ordered by Pfizer pursuant to this Agreement prior to the effective date of such termination, whether or not the due date for such payment is after such effective date of termination, (B) Pfizer's right to receive the Protalix Payment from Protalix, which such payment to be made in accordance with Section 14.5(b), and any payment from Protalix that accrued pursuant to this Agreement prior to the effective date of such termination (subject to the last two sentences of Section 5.21(b)(i)) and (C) 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 termination.

14.5 Effects of Termination or Expiration.

(a) License Grants. The licenses granted to Pfizer under Section 3.1 shall be perpetual and irrevocable such that the expiration or termination of this Agreement for any reason shall not affect or limit any of the rights granted thereunder. Upon the effective date of termination of this Agreement in accordance with this Section 14, except as otherwise provided in Section 14.4, this Section 14.5, and Section 18.4, all other 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.

(b) Deferred Payment. If the Agreement is terminated by Pfizer pursuant to Section 14.1 or by Protalix pursuant to Section 14.3 before Protalix has made the Protalix Payment, Protalix shall pay to Pfizer the Protalix Payment in accordance with Section 6.2. If the Agreement is terminated by Pfizer pursuant to Section 14.2, Protalix shall pay to Pfizer the Protalix Payment within thirty (30) days following the effective date of termination of this Agreement as provided in the Promissory Note.

(c) Confidential Information. Following any termination of this Agreement, each of Pfizer and Protalix shall, upon request of the other party, return or destroy all Protalix Confidential Information and Pfizer 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 14.5.

14.6 Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by Protalix are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The parties agree that Pfizer, as the licensee of intellectual property under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Without limiting the foregoing, Section 365(n) shall apply to any case commenced under Chapter 15 of the U.S. Bankruptcy Code and, if the foreign representative in such a case rejects or repudiates rights of licenses granted under or pursuant to this Agreement, Pfizer shall be entitled to make the election and exercise the rights described in Section 365(n). The parties further agree that, in the event of a rejection of this Agreement by Protalix in any bankruptcy proceeding by or against Protalix under the U.S. Bankruptcy Code or rejection or repudiation by a foreign representative in a foreign bankruptcy proceeding, (a) Pfizer shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the possession of the licensee, shall be promptly delivered to it upon Pfizer's written request therefor, and (b) Protalix shall not interfere with Pfizer's rights to intellectual property and all embodiments of intellectual property, and shall assist and not interfere with Pfizer in obtaining intellectual property and all embodiments of intellectual property from another entity. The term "embodiments" of intellectual property includes all tangible, intangible, electronic or other embodiments of rights and licenses hereunder, including all compounds and products embodying intellectual property, Licensed Products, regulatory filings, clinical studies and related rights, and Technology.

Section 15. INDEMNIFICATION AND INSURANCE

15.1 Indemnification.

(a) Protalix will indemnify, defend and hold Pfizer and Pfizer's Affiliates, and their respective directors, officers and employees harmless from and against all Third Party Claims (defined in Section 15.3 below) and associated Losses, in each case to the extent arising out of:

(i) the breach of any covenant, warranty or representation made by Protalix under this Agreement;

(ii) the negligence, recklessness, or willful misconduct of, or violation of law by, Protalix or any of its Affiliates;

(iii) any acts or omissions of Protalix or any of its Affiliates, agents, consultants or contractors (A) in connection with the research, Development, Manufacture or Commercialization of the Drug Substance or Licensed Product prior to the Effective Date, (B) in connection with the research, Development, Manufacture (including Fill/Finish) or Commercialization of the Drug Substance or Licensed Products in Brazil following the Amendment Effective Date, (C) in connection with the research, Development, Manufacture (including Fill/Finish) or Commercialization of the Drug Substance or Licensed Product prior to the Second Amendment Effective Date and during the Israel Transition Period or (D) in connection with the Manufacture of the Drug Substance for supply to Pfizer pursuant to Section 5;

(iv) (A) any claim made by an [***] against Pfizer for any consideration allegedly owed to an [***] in connection with Commercialization of the Licensed Product in Brazil, or the Technology Transfer Agreement, or (B) any inquiry, investigation, litigation or proceeding by a governmental authority or Third Party regarding any ATME Person in connection with the Commercialization of the Licensed Product in Brazil by Protalix, the Technology Transfer Agreement, or any other actions of an ATME Person on behalf of Protalix; or

(v) any and all claims asserted by [***] against any Pfizer Indemnified Party with respect to the Drug Substance, the Licensed Product [***], including any claims of infringement or misappropriation or for royalties, milestone payments, license fees or other payments due thereunder, in relation to Pfizer's exercise (in accordance with this Agreement) of the license granted hereunder to Pfizer under the Protalix Patent Rights licensed by Protalix from VTIP [***]; provided however, Protalix shall not indemnify, defend and hold Pfizer harmless to extent any such claim asserted by [***] relates to [***] intellectual property that has not been licensed to Protalix under the [***]. For the avoidance of doubt, (a) in no event shall Pfizer be responsible for any royalties, milestone payments, license fees or other payments payable to VTIP under the [***], and (b) Protalix shall be solely responsible to [***] for any amounts owed to [***] under the [***].

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

Protalix shall be obligated to so indemnify, defend and hold Pfizer harmless only to the extent that such Losses (i) do not arise from the negligence, recklessness or willful misconduct of Pfizer and (ii) are not Losses as to which Protalix is entitled to indemnification pursuant to Section 15.1(b).

(b) Pfizer will indemnify, defend and hold Protalix, its Affiliates, and their respective directors, officers and employees harmless from and against all Third Party Claims and associated Losses, to the extent arising out of:

(i) the breach of any covenant, warranty or representation made by Pfizer under this Agreement;

(ii) the negligence, recklessness, or willful misconduct of, or violation of law by, Pfizer or any of its Affiliates; or

(iii) (A) any acts or omissions of Pfizer or any of its Affiliates, agents, consultants or contractors in connection with the research, Development, Manufacture (including Fill/Finish) or Commercialization of the Drug Substance or Licensed Product in the Field inside the Territory (other than Israel or Brazil) after the Effective Date, (B) any acts or omissions of Pfizer or any of its Affiliates, agents consultants or contractors in connection with the research, Development, Manufacture (including Fill/Finish) or Commercialization of the Drug Substance or Licensed Product in the Field in Brazil prior to the Amendment Effective Date, or (C) any acts or omissions of Pfizer or any of its Affiliates, agents, consultants or contractors in connection with the research, Development, Manufacture (including Fill/Finish) or Commercialization of the Drug Substance or Licensed Product in the Field in Israel after the Israel Transition Period.

Pfizer shall be obligated to so indemnify, defend and hold Protalix harmless only to the extent that such Losses (i) do not arise from the negligence, recklessness or willful misconduct of Protalix and (ii) are not Losses as to which Pfizer is entitled to indemnification pursuant to Section 15.1(a).

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

15.3 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 and employees. 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 and employees (the "Indemnified Party") is entitled to indemnification hereunder, then the Indemnified Party shall promptly notify in writing the party obligated to indemnify the Indemnified Party (the "Indemnifying Party") thereof; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

(b) 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 15.1, as applicable, solely for such Third Party Claim and related Losses.

(c) 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. Without limiting the foregoing, the Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld), effect any settlement of any pending or threatened litigation in which the Indemnified Party has sought indemnification hereunder by 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.

15.4 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 PFIZER, PROTALIX OR ANY OF THEIR RESPECTIVE AFFILIATES, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A PARTY'S WILLFUL MISCONDUCT OR INTENTIONAL BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT AND EXCEPT FOR ANY PERSISTENT FAILURE TO SUPPLY PAYMENTS AS EXPRESSLY PROVIDED IN SECTION 5.21. THE FOREGOING SENTENCE SHALL NOT LIMIT THE OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTION 15 OR LIABILITIES RESULTING FROM A BREACH OF THE CONFIDENTIALITY OBLIGATIONS UNDER SECTION 9 ABOVE AND PROVIDED THAT THIS SECTION 15.4 SHALL NOT RELIEVE EITHER PARTY FROM ITS PAYMENT OBLIGATIONS UNDER THIS AGREEMENT.

15.5 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 15 SHALL BE THE SOLE AND EXCLUSIVE REMEDY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY) AVAILABLE TO PROTALIX OR PFIZER FOR THE MATTERS COVERED THEREIN.

15.6 Insurance Requirements. As of the Second Amendment Effective Date, Protalix shall provide and maintain such insurance coverage, in minimum types and amounts as described in subsection (b) below. As of the Second Amendment Effective Date, Pfizer shall self insure or provide and maintain such insurance coverage, in minimum types and amounts as described in subsection (d) below.

(a) Protalix Insurance Generally.

(i) Any and all deductibles for Protalix's insurance policies (the "Protalix Insurance Policies") shall be assumed by, for the account of, and at Protalix's sole risk. All deductibles and self-insured retention amounts shall be assumed by Protalix.

(ii) Such Protalix Insurance Policies shall be primary and non-contributing with respect to any other similar insurance policies available to Pfizer or its Affiliates. Except for employers' liability and property insurance policies, Protalix will add Pfizer and its Affiliates on all such Protalix Insurance Policies as additional insureds with respect to liability incurred by Pfizer or its Affiliates arising from any acts or omissions of Protalix, and Protalix will require that the property insurance policy included in the Protalix Insurance Policies include a waiver of subrogation in favor of Pfizer and its Affiliates.

(iii) Prior to the Second Amendment Effective Date, Protalix has provided Pfizer with original certificates and additional insurance endorsements evidencing the specified insurance coverage, and at each renewal thereof or expiration of any one coverage, whichever occurs first, Protalix shall furnish to Pfizer original certificates and additional insurance endorsements evidencing the specified insurance coverage. Such certificates shall provide that not less than thirty (30) days prior written notice of any policy cancellation or detrimental change shall be given to Pfizer. The certificate(s) of insurance shall be signed by a person authorized by the insurer(s) to bind coverage on its (their) behalf. Protalix shall provide, pay for, and maintain in effect, the Protalix Insurance Policies with a minimum "A-" A.M. Bests rating or S&P minimum of BBB or their substantial equivalent (in the case of such policies in Israel, to the extent such ratings or substantial equivalents are available).

(b) Protalix Insurance Requirements. The insurance required under subsection (a) shall be written for not less than any limits of liability specified herein or as required by law, whichever is greater; Protalix has the right to provide the total limits required by any combination of primary and excess/umbrella coverage; said Protalix insurance to include, without limitation, the following:

(i) Insurance for liability applicable with respect to persons performing the work hereunder and employer's liability insurance covering all claims by or in respect to the employees of Protalix and all subcontractors, providing:

(ii) Employer's liability insurance with a limit of the greater of the equivalent of [***] for each occurrence and in the aggregate in the Protalix Insurance Policies.

(iii) Commercial General/Public Liability insurance with the following limits and forms/endorsements:

(A) Each occurrence and in the aggregate: [***]

(B) Clinical Trials Coverage or Products & Completed Operations Aggregate once products are marketed: $[***].

(C) Pfizer and its Affiliates as additional insureds with respect to any legal liability of Pfizer or its Affiliates, arising out of Protalix's performance hereunder.

If Protalix has care, custody or control of Pfizer property or inventory, Protalix shall be responsible for any loss or damage to it, and provide all risk property coverage included within the Protalix Insurance Policies at full replacement cost for same.

(c) Pfizer Insurance Generally.

(i) Any and all deductibles for Pfizer's insurance policies (the "Pfizer Insurance Policies") shall be assumed by, for the account of, and at Pfizer's sole risk.

(ii) To the extent of its negligence, such Pfizer Insurance Policies shall be primary and non-contributing with respect to any other similar insurance policies available to Protalix or its Affiliates. Except for workers compensation/employers' liability, Pfizer will add Protalix and its Affiliates, as additional insureds, and Pfizer will require that the Pfizer Insurance Policies provide a waiver of subrogation in favor of Protalix and its Affiliates.

(iii) Prior to the Second Amendment Effective Date of the Agreement and, at Protalix's request, at each renewal thereof or expiration of any one coverage, whichever occurs first, Pfizer shall furnish to Protalix original certificates evidencing the specified insurance coverage. Such certificates shall provide that not less than thirty (30) days prior written notice of any policy cancellation or detrimental change shall be given to Protalix. The certificate(s) of insurance shall be signed by a person authorized by the insurer(s) to bind coverage on its (their) behalf. Pfizer shall provide, pay for, and maintain in effect the Pfizer Insurance Policies with minimum "A-" A.M. Bests rated insurance carriers.

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

(d) Pfizer Insurance Requirements. The insurance required under subsection (c) shall be written for not less than any limits of liability specified herein or as required by law, whichever is greater; Pfizer has the right to provide the total limits required by any combination of self insurance, primary and excess/umbrella coverage; said Pfizer Insurance to include, without limitation, the following:

(i) Insurance for liability under the workers' compensation or occupational disease laws of any state or other jurisdiction in which Pfizer performs activities pursuant to this Agreement (or be a qualified self-insurer in those states and jurisdictions) or otherwise applicable with respect to persons performing hereunder and employer's liability insurance covering all claims by or in respect to the employees of Pfizer, providing:

Employer's liability insurance with a limit of [***]

(ii) Commercial General Liability insurance with the following limits and forms/endorsements:

(A) Each occurrence: [***]

(B) Products & Completed Operations Aggregate: [***]

(C) Protalix and its Affiliates as additional insureds with respect to any legal liability of Protalix or its Affiliates, arising out of Pfizer's performance hereunder.

(iii) Umbrella (Excess) Liability Coverage (follow form) in an amount not less than [***] per occurrence.

Section 16. [RESERVED.]

Section 17. GOVERNING LAW AND JURISDICTION

17.1 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.

17.2 Jurisdiction. In the event of any controversy, claim or counterclaim arising out of or relating to this Agreement, the parties shall first attempt to resolve such controversy or claim through good faith negotiations for a period of not less than thirty (30) days following notification of such controversy or claim to the other party. If such controversy or claim cannot be resolved by means of such negotiations during such period, then such controversy or claim shall be resolved by the United States District Court for the Southern District of New York or, in the event federal subject matter jurisdiction is lacking, a New York State court sitting in New York, New York (the "Court"). Each party (a) irrevocably submits to the exclusive jurisdiction of the Court for purposes of any action, suit or other proceeding relating to or arising out of this Agreement and (b) agrees not to raise any objection at any time to the laying or maintaining of

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

the venue of any such action, suit or proceeding in the Court, irrevocably waives any claim that such action, suit or other proceeding has been brought in an inconvenient forum and further irrevocably waives the right to object, with respect to such action, suit or other proceeding, that the Court does not have any jurisdiction over such party. The provisions of the U.N. Convention on Contracts for the International Sale of Goods shall not apply to this Agreement. Protalix hereby irrevocably designates, appoints and empowers CT Corporation System, 111 Eighth Avenue, New York, NY 10011, as its true and lawful agent and attorney-in-fact in its name, place and stead to receive and accept on its behalf service of process in any action, suit or proceeding in the Court with respect to any matters as to which it has submitted to jurisdiction as set forth in the immediately preceding sentence.

SECTION 18.MISCELLANEOUS

18.1 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 Second Amendment 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.

18.2 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.

18.3 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.

18.4 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 Pfizer before the Second Amendment Effective Date with respect to the subject matter hereof, including the Confidential Disclosure Agreement between the parties, dated June 11, 2009 and the Amended Agreement, except as otherwise provided in Section 6.4. All Confidential Information disclosed by either party to the other party prior to the Second Amendment 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.

18.5 Survival. The provisions of Section 3.1 (Exclusive License), Section 3.3 (Non-Assertion of Rights), Section 3.4 (Sublicensing and Subcontracting), Section 3.6(a) (No Implied License; Brazil Activities), Section 4.1(f) (Assignment of Contracts), Section 4.1(g)(i) (Responsibility), Section 4.1(l) (Recalls or Other Corrective Action), Section 4.2(a) (Commercialization and Pricing), Section 4.4 (Pfizer Trademarks), Section 4.5 (Use of Names), Section 5.15 (Records and Audits), Section 5.21(f) (Damages), Section 5.23 (Manufacturing Transition Assistance), Section 6.2 (Deferred Payment), Section 8 (Patents and Infringement), Sections 9.1 and 9.2 (Confidentiality), Section 9.3 (Publication), Section 9.4 (Publicity), Section 10.5 (Disclaimer of Warranty), Section 11.1 (Restrictions on Transfers and Liens), Section 11.2 (Third Party Licenses and Agreements), Section 11.4 (Coordinating outside the Territory), Section 14.4 (Continuing and Accrued Obligations and Surviving Provisions), Section 14.5 (Effect of Termination or Expiration), Section 14.6 (Bankruptcy), Section 15 (Indemnification) other than Section 15.6 (Insurance Requirements), Section 17 (Governing Law and Jurisdiction) and this Section 18 (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.

18.6 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; (ii) to a Third Party where a party or its Affiliate is required, or makes a good faith determination based on advice of counsel, to divest a Licensed Product in order to comply with Law or the order of any Governmental Authority as a result of a merger or acquisition; or (iii) 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.

(b) Any purported assignment in violation of this Section 18.6 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

(c) Pfizer may assume this Agreement in any proceeding under the U.S. Bankruptcy Code upon satisfaction of the conditions set forth in U.S. Bankruptcy Code Section 365(b)(1).

18.7 Divestiture. For the avoidance of doubt, nothing in this Section 18.7 shall prevent Pfizer from assigning its rights and obligations under this Agreement pursuant to Section 18.6.

(a) Notwithstanding anything to the contrary contained in this Agreement, to the extent related to or arising in connection with a divestiture (whether by sale, spin-off, or similar transaction) by Pfizer of all or any portion of a Pfizer business or business unit (a "Divestiture"), Pfizer may, without prior written notice to or consent of Protalix, without any penalty, and at no additional cost to Pfizer or to any affiliate of Pfizer or to the company or the group of companies resulting from such Divestiture (collectively, such companies, the "Resulting Companies"): (1) assign its rights and obligations under this Agreement, in whole or in part to one or more of the Resulting Companies, or (2) split and assign, in whole or in part, its rights and obligations under this Agreement to one or more of the Resulting Companies so as to retain the benefits of this Agreement for both Pfizer and the applicable Resulting Companies following such Divestiture; provided that [***]

(b) From and after any partial assignment or split the rights and obligations of Pfizer hereunder shall be divided between Pfizer and the Resulting Companies to whom such rights and obligations are transferred as specified by Pfizer, such that all such rights and obligations related to the business of the applicable Resulting Companies shall be enforceable only by and against the applicable Resulting Companies, and all other such rights and obligations shall be enforceable only by and against Pfizer. Protalix will, [***], work cooperatively with Pfizer and the applicable Resulting Companies to ensure a smooth and orderly transition, including, to the extent requested by Pfizer, entering into separate agreements with Pfizer and the applicable Resulting Companies on substantially the same terms and conditions (as adjusted to take into account the nature of the separate contracts while maintaining the economic, business and other purposes of the Agreement).

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

18.9 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, express overnight courier or delivered personally to the following addresses of the respective parties:

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

If to Protalix: Protalix Ltd.
2 Snunit Street
Science Park
P.O.B. 455
Carmiel 20100, Israel
Attention: Chief Executive Officer

If to Pfizer: Pfizer Inc.
235 East 42nd Street
New York, New York, 10017-5755
U.S.A.
Attention: President of the Global Innovative Products Business Unit

with a copy to:
Pfizer Inc.
235 East 42nd Street
New York, New York, 10017-5755
U.S.A.
Attention: Chief Counsel, Global Innovative Products Business Unit

Pfizer Inc.
235 East 42nd Street
New York, New York, 10017-5755
U.S.A.
Attention: Senior Vice President, Business 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 delivery to the overnight courier if sent by overnight courier. A party may change its address listed above by sending notice to the other party in accordance with this Section 18.9.

18.10 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.

18.11 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.

18.12 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. Pfizer may use one or more of its Affiliates to exercise its rights or perform its obligations and

duties hereunder, provided that Pfizer shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

18.13 Corporate Integrity Agreement. Protalix acknowledges that (a) Pfizer develops and promotes its products in compliance with the statutes, regulations and written directives of Medicare, Medicaid and all other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) and with the statutes, regulations, and written directives of the Food and Drug Administration, and (b) Pfizer shall not be obligated to take any action pursuant to this Agreement that it believes, in its sole discretion, constitutes a violation of any of Pfizer's obligations set forth in subsection (a) above or such Corporate Integrity Agreement.

18.14 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.

18.15 Headings. Headings in this Agreement are included herein for ease of reference only and shall have no legal effect. References to the parties, Sections, Schedules, and Exhibits are to the parties, Sections, Schedules and Exhibits to and of this Agreement unless otherwise specified.

18.16 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.

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

Protalix Ltd.	Pfizer Inc.
By : /s/ Moshe Manor	By: /s/ Michael Goettler
Name: Moshe Manor Title: President and Chief Executive Officer	Name :Michael Goettler Title: Global Commercial Officer, Senior Vice President

[***]

Protalix Biotherapeutics, Inc.

By : /s/ Moshe Manor

Name: Moshe Manor
Title: President & Chief Executive Officer

Date: October 12, 2015

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

EXHIBIT 31.1

CERTIFICATION

I, Dror Bashan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 13, 2025

/s/ Dror Bashan
Dror Bashan
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION

I, Gilad Mamlok, 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 13, 2025

/s/ Gilad Mamlok
Gilad Mamlok
Sr. Vice President & Chief Financial Officer,
Treasurer

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2025 as filed with the Securities and Exchange Commission (the "Report"), I, Dror Bashan, President and Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for 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 13, 2025

/s/ Dror Bashan
Dror Bashan
President and Chief Executive Officer

EXHIBIT 32.2

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2025 as filed with the Securities and Exchange Commission (the "Report"), I, Gilad Mamlok, Senior Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

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

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

Date: November 13, 2025

/s/ Gilad Mamlok
Gilad Mamlok
Senior Vice President and Chief Financial Officer