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, 2022

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 10, 2022, approximately 50,665,598 shares of the Registrant's common stock, $0.001 par value, were outstanding.

FORM

10-Q
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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, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,720	$ 38,985
Short-term bank deposits	10,091	-
Accounts receivable – Trade	8,651	3,442
Other assets	1,736	1,285
Inventories	14,562	17,954
Total current assets	$ 45,760	$ 61,666
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,418	$ 2,077
Property and equipment, net	4,677	4,962
Operating lease right of use assets	4,854	4,960
Total assets	$ 56,709	$ 73,665
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,639	$ 6,986
Other	12,870	16,433
Operating lease liabilities	1,000	1,207
Contracts liability	14,793	8,550
Total current liabilities	$ 34,302	$ 33,176
LONG TERM LIABILITIES:		
Convertible notes	$ 28,111	$ 27,887
Contracts liability	-	11,790
Liability for employee rights upon retirement	1,779	2,472
Operating lease liabilities	4,031	4,376
Total long term liabilities	$ 33,921	$ 46,525
Total liabilities	$ 68,223	$ 79,701
COMMITMENTS		
CAPITAL DEFICIENCY	(11,514)	(6,036)
Total liabilities net of capital deficiency	$ 56,709	$ 73,665

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, 2022	September 30, 2021	September 30, 2022	September 30, 2021
REVENUES FROM SELLING GOODS	$ 21,222	$ 12,260	$ 8,812	$ 4,506
REVENUES FROM LICENSE AND R&D SERVICES	17,799	17,541	5,371	7,548
TOTAL REVENUE	39,021	29,801	14,183	12,054
COST OF GOODS SOLD (1)	(17,195)	(13,201)	(7,074)	(3,703)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(23,732)	(22,093)	(7,386)	(7,282)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(8,613)	(9,263)	(2,848)	(2,954)
OPERATING LOSS	(10,519)	(14,756)	(3,125)	(1,885)
FINANCIAL EXPENSES	(1,879)	(6,613)	(639)	(2,410)
FINANCIAL INCOME	1,211	403	197	96
FINANCIAL EXPENSES, NET	(668)	(6,210)	(442)	(2,314)
OTHER INCOME	-	51	-	-
NET LOSS FOR THE PERIOD	$ (11,187)	$ (20,915)	$ (3,567)	$ (4,199)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.24)	$ (0.48)	$ (0.07)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	47,582,733	43,761,769	49,498,105	45,556,647
(1) Includes share-based compensation	$ 58	$ 217	$ 36	$ 65
(2) Includes share-based compensation	$ 275	$ 524	$ 114	$ 154
(3) Includes share-based compensation	$ 1,213	$ 1,216	$ 272	$ 344

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

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

	Common Stock (1)	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
Balance at January 1, 2021	**34,765,280**	**$ 35**	**$ 320,280**	**$ (347,352)**	**$ (27,037)**
Changes during the nine-month period ended September 30, 2021:					
Issuance of common stock, net of issuance cost	8,749,999	9	37,616		37,625
Issuance of common stock under the Sales Agreement, net	1,867,552	2	8,573		8,575
Share-based compensation related to stock options			1,176		1,176
Share-based compensation related to restricted stock awards			781		781
Exercise of warrants	173,816	*			*
Reacquisition of equity component of convertible notes			(12,019)		(12,019)
Equity component of convertible notes, net of transaction costs			12,027		12,027
Net loss for the period				(20,915)	(20,915)
Balance at September 30, 2021	**45,556,647**	**$ 46**	**$ 368,434**	**$ (368,267)**	**$ 213**
Balance at January 1, 2022	**45,556,647**	**$ 46**	**$ 368,852**	**$ (374,934)**	**$ (6,036)**
Changes during the nine-month period ended September 30, 2022:					
Issuance of common stock under the Sales Agreement, net	3,841,479	4	4,157		4,161
Share-based compensation related to stock options			592		592
Share-based compensation related to restricted stock awards	759,482	*	954		954
Exercise of warrants	1,000	*	2		2
Net loss for the period				(11,187)	(11,187)
Balance at September 30, 2022	**50,158,608**	**$ 50**	**$ 374,557**	**$ (386,121)**	**$ (11,514)**
Balance at June 30, 2021	**45,556,647**	**$ 46**	**$ 367,863**	**$ (364,068)**	**$ 3,841**
Changes during the three-month period ended September 30, 2021:					
Reacquisition of equity component of convertible notes			(12,019)		(12,019)
Equity component of convertible notes, net of transaction costs			12,027		12,027
Share-based compensation related to stock options			344		344
Share-based compensation related to restricted stock awards			219		219
Net loss for the period				(4,199)	(4,199)
Balance at September 30, 2021	**45,556,647**	**$ 46**	**$ 368,434**	**$ (368,267)**	**$ 213**
Balance at June 30, 2022	**48,712,952**	**$ 49**	**$ 372,616**	**$ (382,554)**	**$ (9,889)**
Changes during the three-month period ended September 30, 2022:					
Issuance of common stock under the Sales Agreement, net	1,445,656	1	1,519		1,520
Share-based compensation related to stock options			298		298
Share-based compensation related to restricted stock awards			124		124
Net loss for the period				(3,567)	(3,567)
Balance at September 30, 2022	**50,158,608**	**$ 50**	**$ 374,557**	**$ (386,121)**	**$ (11,514)**

* Represents an amount equal to less than $1.

(1) Common stock, $0.001 par value; Authorized – as of September 30, 2022 and 2021 – 144,000,000 and 120,000,000 shares, respectively.

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

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

	Nine Months Ended	
	September 30, 2022	September 30, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (11,187)	$ (20,915)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,546	1,957
Depreciation	811	859
Financial income, net (mainly exchange differences)	(1,083)	118
Changes in accrued liability for employee rights upon retirement	(391)	100
Loss (gain) on amounts funded in respect of employee rights upon retirement	6	(75)
Gain on sale of fixed assets	-	(51)
Loss on extinguishment of convertible notes	-	831
Amortization of debt issuance costs and debt discount	224	2,569
Changes in operating assets and liabilities:		
Increase (decrease) in contracts liability (including non-current portion)	(5,547)	13,945
Increase in accounts receivable-trade and other assets	(5,692)	(4,075)
Changes in operating lease right of use assets	(30)	168
Decrease (increase) in inventories	3,392	(1,648)
Increase (decrease) in accounts payable and accruals	(4,438)	1,070
Decrease in other long term liabilities	-	(51)
Net cash used in operating activities	$ (22,389)	$ (5,198)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in bank deposits	$ (16,000)	$ (37,835)
Proceeds from sale of short-term deposits	6,000	20,000
Purchase of property and equipment	(415)	(1,011)
Proceeds from sale of property and equipment	-	53
Decrease in restricted deposit	-	359
Amounts paid (funded) in respect of employee rights upon retirement, net	427	(81)
Net cash used in investing activities	$ (9,988)	$ (18,515)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment for convertible notes redemption and transactions costs	-	$ (25,990)
Payment for promissory note	-	(4,086)
Proceeds from issuance of common stock and warrants, net	-	37,625
Proceeds from issuance of common stock under the Sales Agreement, net	$ 4,161	8,575
Exercise of warrants	2	-
Net cash provided by financing activities	$ 4,163	$ 16,124
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (51)	$ (34)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(28,265)	(7,623)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	38,985	18,265
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 10,720	$ 10,642

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

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

(Continued) – 2

	Nine Months Ended	
	September 30, 2022	**September 30, 2021**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 205	$ 387
Operating lease right of use assets obtained in exchange for new operating lease liabilities	$ 396	$ 309
Transactions costs in connection with the exchange of convertible notes	$ -	$ 774
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$ 2,198	$ 3,288
Interest received	$ 136	$ 445

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

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

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

The most advanced investigational drug in the Company's product pipeline is pegunigalsidase alfa, or PRX-102, a therapeutic protein candidate for the treatment of Fabry disease, a rare, genetic lysosomal disorder, which is the subject of a phase III clinical program. The PRX-102 Phase III clinical program includes three separate studies, referred to as the *BALANCE* study, the *BRIDGE* study and the *BRIGHT* study, each of which has been completed. The studies were designed to evaluate the potential for improved efficacy and better quality of life for adult patients with Fabry disease and to evaluate the safety of the Company's drug/therapy. In addition, the Phase III clinical program includes two extension studies in which subjects that participated in the Company's phase I/II clinical trials and phase III clinical trials may enroll and continue to be treated with PRX-102.

On November 9, 2022, the Company, together with its development and commercialization partner for PRX-102, Chiesi Farmaceutici S.p.A. ("Chiesi"), resubmitted to the U.S. Food and Drug Administration (the "FDA") a biologics license application ("BLA") for PRX-102 for the potential treatment of adult patients with Fabry disease. The initial BLA for PRX-102 was submitted to the FDA on May 27, 2020 under the FDA's Accelerated Approval pathway, and was subsequently accepted by the FDA and granted Priority Review designation. However, in April 2021, the FDA issued a Complete Response Letter (CRL) in response to the initial BLA. In preparation for the BLA resubmission, the Company and Chiesi participated in a Type A (End of Review) meeting with the FDA on September 9, 2021. As part of the meeting minutes provided by the FDA, which included the preliminary comments and meeting discussion, the FDA, in principle, agreed that the data package proposed to the FDA for a BLA resubmission has the potential to support a traditional approval of PRX-102 for the treatment of Fabry disease. The data package in the BLA resubmission, given the change in the regulatory landscape in the United States, includes the final two-year analyses of the Company's phase III *BALANCE* clinical trial of PRX-102 (the "*BALANCE* study"), which were completed in July 2022, and long-term data from the Company's open-label extension study of PRX-102 in adult patients treated with a 2 mg/kg every four weeks dosage of PRX-102.

On February 7, 2022, the Company, together with Chiesi, submitted a Marketing Authorization Application ("MAA") for PRX-102 to the European Medicines Agency ("EMA") which was subsequently validated by the EMA. The submission was made after the October 8, 2021 meeting the Company held, together with Chiesi, with the Rapporteur and Co-Rapporteur of the EMA regarding PRX-102.

The MAA submission includes a comprehensive set of preclinical, clinical and manufacturing data compiled from the Company's completed and ongoing clinical studies evaluating PRX-102 as a potential alternation treatment for adult patients with Fabry disease. The submission was supported by the 12–month interim data analysis generated from the *BALANCE* study. Data generated from the Company's completed phase III *BRIDGE* clinical trial (the "*BRIDGE* study"), the Company's phase I/II clinical trial in naive or untreated patients, and from the Company's extension studies with 1 mg/kg every two weeks were also included in the submission. In addition, the MAA includes data from the Company's completed 12–month switch–over phase III *BRIGHT* clinical trial in adult patients with Fabry disease treated with a 2 mg/kg every four weeks dosage (the "*BRIGHT* study") to support an additional potential treatment regimen for Fabry patients. As part of the EMA review process, Chiesi and the Company received the Day 120 list of questions in June 2022, and the full response package thereto was submitted to the EMA in September 2022 (following a 3-month clock-stop period). An essential portion of the response included the submission of the final analysis of the two-year

PROTALIX BIOTHERAPEUTICS, INC.
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BALANCE study (the final Clinical Study Report), and an interim analysis of the Company's long-term, open-label extension study of PRX-102 in adult patients with Fabry disease treated with the 2 mg/kg every four weeks dosage.

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

(1) alidornase alfa, or PRX-110, a proprietary plant cell recombinant human Deoxyribonuclease 1, or DNase, which has successfully completed a phase II efficacy and safety study; the Company is continuing to evaluate potential strategic marketing partnerships and collaboration programs with biotechnology and pharmaceutical companies for this product candidate for various respiratory indications;

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

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

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

On July 2, 2021, the Company entered into an At The Market Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC, as the Company's sales agent (the "Agent") which was amended on May 2, 2022. Pursuant to the terms of the Sales Agreement, the Company may sell from time to time through the Agent shares of its common stock, par value $0.001 per share (the "Common Stock"), having an aggregate offering price of up to $20.0 million (the "ATM Shares"). Upon execution of the Sales Agreement, the Company terminated the ATM Equity Offering^{SM} Sales Agreement it had entered into on October 1, 2020 with BofA Securities, Inc. ("BofA Securities"). During the term of the sales agreement with BofA Securities, the Company sold a total of 3,296,123 shares of Common Stock for total gross proceeds of approximately $13.8 million. As of September 30, 2022, shares of Common Stock for total gross proceeds of approximately $15.6 million remain available to be sold under the Sales Agreement.

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

Under each of the Chiesi Ex-US Agreement and the Chiesi US Agreement (collectively, the "Chiesi Agreements"), Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of each agreement. In addition, under the Chiesi Ex-US Agreement, Protalix Ltd. is entitled to additional payments of up to $25.0 million in pegunigalsidase alfa development costs, capped at $10.0 million per year, and to receive additional payments of up to $320.0 million, in the aggregate, in regulatory and commercial milestone payments. Under the Chiesi US Agreement, Protalix Ltd. is entitled to payments of up to a maximum of $20.0 million to cover development costs for pegunigalsidase alfa, subject to a maximum of $7.5 million per year, and to receive additional payments of up to a maximum of $760.0 million, in the aggregate, in regulatory and commercial milestone payments. To date, Protalix Ltd. has received the full amount of development costs to which it is entitled under the Chiesi Agreements.

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

On May 13, 2021, the Company signed a binding term sheet with Chiesi pursuant to which the Company and Chiesi amended the Chiesi Agreements in order to provide the Company with near-term capital. In accordance with the term

PROTALIX BIOTHERAPEUTICS, INC.
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(Unaudited)

sheet, Chiesi made a $10.0 million payment to the Company in the second quarter of 2021 in exchange for a $25.0 million reduction in a longer term regulatory milestone payment in the Chiesi EX-US Agreement. All other regulatory and commercial milestone payments remain unchanged. The Company also agreed to negotiate certain manufacturing related matters.

Since its approval by the FDA, taliglucerase alfa has been marketed by Pfizer Inc. ("Pfizer") under the initial Exclusive License and Supply Agreement (the "Pfizer Agreement"). In October 2015, Protalix Ltd. and Pfizer entered into an amended exclusive license and supply agreement (the "Amended Pfizer Agreement") pursuant to which the Company sold to Pfizer its share in the collaboration created under the Pfizer Agreement for the commercialization of Elelyso. As part of the sale, the Company agreed to transfer its rights to Elelyso in Israel to Pfizer while gaining full rights to it in Brazil. Under the Amended Pfizer Agreement, Pfizer is entitled to all of the revenues, and is responsible for 100% of expenses globally for Elelyso, excluding Brazil where the Company is responsible for all expenses and retains all revenues.

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

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

The Company believes that its cash and cash equivalents and short-term bank deposits as of September 30, 2022 are sufficient to satisfy the Company's capital needs for at least 12 months from the date that these financial statements are issued. In addition, under the terms of the Company's outstanding 7.50% Senior Secured Convertible Notes due 2024 (the "2024 Notes"), the Company is required to maintain a minimum cash balance of at least $7.5 million.

b. Basis of presentation

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

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2021, filed by the Company with the U.S. Securities and Exchange Commission (the "Commission"). The comparative balance sheet at December 31, 2021 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, 2021.

c. Loss per share

Basic and diluted loss per share ("LPS") are computed by dividing net loss by the weighted average number of shares of Common Stock attributable to common stockholders outstanding for each period. The calculation of diluted LPS does

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

not include 33,922,624 and 33,295,154 shares of Common Stock underlying outstanding options and shares of Common Stock issuable upon conversion of the outstanding 2024 Notes and the exercise of outstanding warrants for the three and nine months ended September 30, 2022, respectively, and 27,962,842 and 26,847,081 shares of Common Stock underlying outstanding options and shares of Common Stock issuable upon conversion of the Company's then outstanding 7.50% Senior Secured Convertible Notes due 2021 (the "2021 Notes") and the exercise of outstanding warrants for the three and nine months ended September 30, 2021, respectively, because their effect would be anti-dilutive.

d. Revenue recognition

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

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

1. Revenues from selling products

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

2. Revenue from Chiesi Agreements

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

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

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

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

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

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

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

3. Revenue from R&D services

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

NOTE 2 - INVENTORIES

Inventories at September 30, 2022 and December 31, 2021 consisted of the following:

(U.S. dollars in thousands)	September 30, 2022	December 31, 2021
Raw materials	$ 3,664	$ 3,166
Work in progress	2,619	3,262
Finished goods	8,279	11,526
Total inventory	$ 14,562	$ 17,954

NOTE 3 – FAIR VALUE MEASUREMENT

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

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

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

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

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

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

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

As of September 30, 2022, the carrying amounts of short-term deposits approximate their fair values due to the stated interest rates, which approximate market rates.

Based on a Level 3 measurement, as of September 30, 2022, the fair value of the $28.75 million aggregate principal amount of the Company’s outstanding 2024 Notes is approximately $30.9 million. The value of these notes was estimated by implementing the binomial model. The liability component was valued based on the Income Approach. The following parameters were used:

	2024 Notes
Stock price (USD)	1.04
Expected term	1.92
Risk free rate	4.26 %
Volatility	75.32 %
Yield	14.18 %

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NOTE 4 – REVENUES

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

(*U.S. dollars in thousands*)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Pfizer	$ 4,541	$ 1,135	$ 11,279	$ 7,883
Brazil	$ 1,708	$ 3,200	$ 7,162	$ 4,188
Chiesi	$ 2,563	$ 171	$ 2,781	$ 189
Total revenues from selling goods	$ 8,812	$ 4,506	$ 21,222	$ 12,260
Revenues from license and R&D services	$ 5,371	$ 7,548	$ 17,799	$ 17,541

NOTE 5 – SHARE CAPITAL

a) Authorized Capital

On June 30, 2022, the Company held its 2022 Annual Meeting of Stockholders (the "Annual Meeting"). At the Annual Meeting, the Company's stockholders, among other matters, approved an amendment to the Company's Certificate of Incorporation, as amended, to increase the number of shares of Common Stock authorized for issuance from 120,000,000 to 144,000,000 (the "Charter Amendment"). The Charter Amendment was filed with the Secretary of State of the State of Delaware on August 2, 2022.

b) Stock based compensation

1) On February 25, 2022, the Company granted, with the approval of the Company's compensation committee, the following:

   I. 637,531 shares of restricted Common Stock to its President, Chief Executive Officer under the Company's Amended and Restated 2006 Employee Stock Incentive Plan, as amended (the "Plan"). The Company estimated the fair value of the restricted stock on the date of grant to be approximately $523,000.

   II. 121,951 shares of restricted Common Stock to its Sr. Vice President, Chief Financial Officer under the Plan. The Company estimated the fair value of the restricted stock on the date of grant to be approximately $100,000.

2) On June 30, 2022, the Company's stockholders, among other matters, adopted amendments to the Plan to increase the number of shares of Common Stock available under the Plan from 5,725,171 shares to 8,475,171 shares and to amend certain other terms of the Plan.

3) On June 30, 2022, the Company granted 10-year options to purchase 40,000 shares of Common Stock to a new director serving on the Company's Board of Directors under the Plan. The options have an exercise price equal to $1.09 per share and vest over a four-year period in 16 equal quarterly increments. Vesting of the options granted to the director 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 fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $32,000.

4) On August 1, 2022, the Company granted 10-year options to purchase 160,000 shares of Common Stock to a new employee of the Company under the Plan. The options have an exercise price equal to $1.06 per share and vest over a four-year period in 16 equal quarterly increments. The Company estimated the fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $124,000.

PROTALIX BIOTHERAPEUTICS, INC.
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5) On September 7, 2022, the Company granted, with the approval of the Company's compensation committee, 10-year options to purchase 3,280,000 shares of Common Stock, in the aggregate, to certain of the Company's officers, directors and other employees under the Plan. The options have an exercise price equal to $1.03 per share and vest over a four-year period in 16 equal quarterly increments. Vesting of the options granted to executive officers and directors 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 date of grant using the Black-Scholes option-pricing model to be approximately $2.5 million.

The fair value of each option granted is estimated at the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

Stock price (USD)	1.03	
Exercise price (USD)	1.03	
Risk free rate	3.32	%
Volatility	85.94	%
Dividend yield	0	%
Expected life (Years)	6	

c) At-the-Market (ATM) Offering

During the nine and three months ended September 30, 2022, the Company sold, in the aggregate, 3,841,479 and 1,445,656 shares of Common Stock, respectively, under the Sales Agreement. The Company generated aggregate gross proceeds equal to approximately $4.4 million and $1.6 million, respectively, in connection with such sales.

NOTE 6 – COMMITMENTS

On August 29, 2022, the Company entered into a Fill/Finish Agreement (the "F/F Agreement") and a Letter Agreement (the "Letter Agreement"), in each case with Chiesi. The Company 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 the Company with commercial fill/finish services for PRX-102, including to support the anticipated global launch of PRX-102. The F/F Agreement shall continue in force until December 31, 2025, unless terminated earlier in accordance with the terms of the F/F Agreement and the term may be extended by mutual agreement for an additional period of seven years upon mutual written agreement prior to expiration of the initial term.

NOTE 7 – SUBSEQUENT EVENTS

During October and November 2022, the Company sold, in the aggregate, 506,990 shares of Common Stock under the Sales Agreement. The Company generated aggregate gross proceeds equal to approximately $530,442 in connection with such sales.

On October 13, 2022, the Company collected approximately 1.7 million from sales to Brazil. In October and November 2022, the Company collected approximately $2.3 million, in the aggregate, from sales to Pfizer. On October 26, 2022, the Company collected approximately $1.2 million from expense reimbursements in connection with its collaboration with Chiesi.

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, 2021. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements within the meanings of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to our company or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements as a result of several factors.

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

- the risk that the FDA will find that the resubmitted BLA for PRX-102 is incomplete or not properly reviewable at the time of submission and, accordingly, refuse to file the resubmitted BLA or request additional information;

- risks related to the acceptance by the FDA of the resubmitted BLA for PRX-102, and the timing, progress and likelihood of final approval by the FDA and the EMA of the resubmitted BLA and of the MAA, respectively, for PRX-102, and, if approved, whether the use of PRX-102 will be commercially successful;

- likelihood that the FDA, EMA or other applicable health regulatory authorities will approve an alternative dosing regimen;

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

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

- the risk that the FDA, EMA, or other foreign regulatory authorities may not accept or approve a marketing application we file for any of our other product candidates, and other risks relating to the review process;

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

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

- 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 maintain and 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 our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness;
- risks relating to changes to interim, topline or preliminary data from clinical trials that we announce or publish;
- 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;
- delays in our preparation and filing of applications for regulatory approval; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;
- the impact of development of competing therapies and/or technologies by other companies and institutions;
- potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage;
- risks related to our supply of drug product to Pfizer;
- risks related to our expectations with respect to the potential commercial value of our product and product candidates;
- risks relating to the compliance by Fiocruz with its purchase obligations under our supply and technology transfer agreement, which may have a material adverse effect on us and may also result in the termination of such agreement;
- the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties;
- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere;
- and the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of certain regulatory authorities and of certain of our suppliers, collaborative partners, licensees, clinical trial sites, distributors and customers.

Recent Company Developments

- On November 9, 2022, we, together with Chiesi, resubmitted the BLA for PRX-102 for the potential treatment of adult patients with Fabry disease.
- On August 29, 2022, we entered into the F/F Agreement and the Letter Agreement, in each case with Chiesi.

In light of recent developments relating to the COVID-19 pandemic, the focus of healthcare providers and hospitals on fighting the virus, and consistent with the FDA's updated industry guidance for conducting clinical trials issued on March 18, 2020, we and our contract research organizations have made certain adjustments to the operation of our clinical trials in an effort to ensure the monitoring and safety of patients and minimize risk to trial integrity during the pandemic and generally, and we may need to make adjustments again in the future.

We are in close contact with our principal investigators and clinical sites and our clinical research organizations, which are primarily located in the United States and Europe, and to date, the COVID-19 pandemic has had a minimal effect on the performance of the phase III clinical trials of PRX-102 as many of the patients were already treated in home care settings. We were able to complete all three of the clinical trials.

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

ProCellEx: Our Proprietary Protein Expression System

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

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

- We are the first and only company to gain FDA approval of a protein produced through plant cell-based expression. Our ProCellEx platform uses flexible polyethylene disposable bioreactors and is optimized for plant cell cultures. As opposed to the large stainless-steel bioreactors commonly used for recombinant protein production, our ProCellEx bioreactors are easy to use and maintain and allow for the major advantage of rapid horizontal scale-up.

Plant Cell Production Advantages

Large-Scale Plant Cell Production Advantages

- Rapid product roll-out and development
- No risk of viral contamination from mammalian components
- Manufacturing maintained at room temperature
- Highly tolerant of small changes in production conditions, including Ph and temperature
- Easy to use and maintain, with no requirement for complicated monitors
- Maintain production parameter constant → high reproducibility
- Independent, separately controlled, disposable bioreactors - no "cross talking"
- Rapid and flexible horizontal scale-up in accordance with changing production needs

Mammalian Cell Expression

Chinese Hamster Ovary (CHO) cell lines

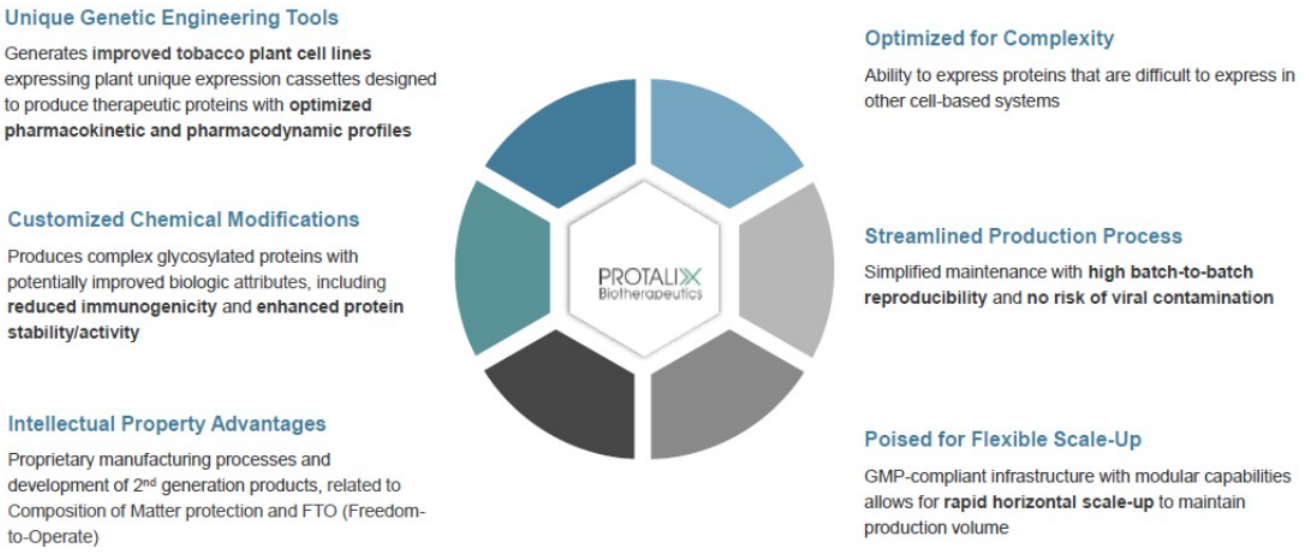
- High set-up costs involving large bioreactors
- Cell cultures require a complex medium; small changes in composition may affect product characteristics
- Require highly controlled growth conditions in the bioreactor (e.g., Ph., temp and CO_2)
- Susceptibility to viral contaminations

Bacteria and Yeast Cell Expression

Bacteria or yeast cell lines

- Limited to non-glycosylated simple proteins
- Cannot produce antibodies, enzymes, and other complex proteins

ProCellEx®: Protalix's Differentiated Plant Cell Protein Expression Platform



Product Pipeline

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

PRX-102 is our lead product candidate and we expect it to be the primary subject of our development efforts in the short-term. It is our proprietary, investigational, plant cell culture expressed enzyme, and a chemically modified stabilized version of, the recombinant α-Galactosidase-A protein, a lysosomal enzyme, under development for the treatment of Fabry disease. Fabry disease is a serious life-threatening rare genetic disorder. Fabry patients lack α-galactosidase-A resulting in the progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide, or Gb_3, in blood vessel walls throughout their body. The abnormal storage of Gb_3 increases with time. The ultimate consequences of Gb_3 deposition range from episodes of pain and impaired peripheral sensation to end-organ failure, particularly of the kidneys, but also of the heart and the cerebrovascular system. Fabry disease occurs in one person per 40,000 to 60,000 males. The global market for Fabry disease was approximately $1.9 billion in 2021, is forecasted to be approximately $2.1 billion in 2022, and is forecasted to grow at a CAGR of approximately 10% from 2020-2027.

On November 9, 2022, we, together with Chiesi, resubmitted to the FDA a BLA for PRX-102 for the potential treatment of adult patients with Fabry disease. The initial BLA for PRX-102 was submitted to the FDA on May 27, 2020 under the FDA's Accelerated Approval pathway, and was subsequently accepted by the FDA and granted Priority Review designation. However, in April 2021, the FDA issued a CRL in response to the initial BLA. In preparation for the BLA resubmission, we and Chiesi participated in a Type A (End of Review) meeting with the FDA on September 9, 2021. As part of the meeting minutes provided by the FDA, which included the preliminary comments and meeting discussion, the FDA, in principle, agreed that the data package proposed to the FDA for a BLA resubmission has the potential to support a traditional approval of PRX-102 for the treatment of Fabry disease. The data package in the BLA resubmission, given the change in the regulatory landscape in the United States, includes the final two-year analyses of our *BALANCE* study, which were completed in July 2022, and long-term data from our open-label extension study of PRX-102 in adult

patients treated with a 2 mg/kg every four weeks dosage of PRX-102. The initial BLA included a comprehensive set of preclinical, clinical and manufacturing data compiled from our completed phase I/II clinical trial of PRX-102, including the related extension study, interim clinical data from our *BRIDGE* study and safety data from our on-going clinical studies of PRX-102 in adult patients receiving 1 mg/kg every two weeks.

The CRL did not report any concerns relating to the potential safety or efficacy of PRX-102 in the submitted data package. In the CRL, the FDA noted that an inspection of our manufacturing facility in Carmiel, Israel, including the FDA's subsequent assessment of any related FDA findings, is required before the FDA can approve a resubmitted BLA. Due to travel restrictions, the FDA was unable to conduct the required inspection during the review cycle. The FDA explained in the letter that it will continue to monitor the public health situation as well as travel restrictions, and is actively working to define an approach for scheduling outstanding inspections. With respect to the third-party facility in Europe at which fill and finish processes are performed for PRX-102, due to COVID-19, the FDA reviewed records under Section 704(a)(4) of the U.S. Federal Food, Drug, and Cosmetic Act in lieu of a pre-licensing inspection. In the CRL, the FDA stated that it will communicate remaining issues to the facility in order to seek prompt resolution of any pending items. In addition to the foregoing, in the CRL, the FDA noted that Fabrazyme® (agalsidase beta), a therapy used to treat Fabry patients (marketed by Sanofi after the acquisition of Genzyme), was recently converted to full approval and is now an "available therapy," which must be addressed in the context of any potential resubmission of a BLA for PRX-102.

On February 7, 2022, we, together with Chiesi, submitted the PRX-102 MAA to the EMA, and the EMA and subsequently validated the submission. The submission was made after the October 8, 2021 meeting we held, together with Chiesi, with the Rapporteur and Co-Rapporteur of the EMA regarding PRX-102. At the meeting, we and Chiesi discussed the scope of the anticipated MAA submission for the European Union, and the Rapporteur and Co-Rapporteur were generally supportive of the planned MAA submission. The MAA submission includes a comprehensive set of preclinical, clinical and manufacturing data compiled from our completed and ongoing clinical studies evaluating PRX-102 as a potential alternative treatment for adult patients with Fabry disease. The submission was supported by the 12–month interim data analysis generated from our *BALANCE* study, which was released in June 2021. Data generated from the completed *BRIDGE* study, the phase I/II clinical trial in naive or untreated patients, and from the extension studies with 1 mg/kg every two weeks were also included in the submission. In addition, the MAA includes data from the completed 12–month switch–over *BRIGHT* study adult patients with Fabry disease treated with the 2 mg/kg every four weeks dosage to support an additional potential treatment regimen for patients with Fabry disease. As part of the EMA review process, we and Chiesi received the Day 120 list of questions in June 2022, and the full response package thereto was submitted to the EMA in September 2022 (following a 3-month clock-stop period). An essential portion of the response included the submission of the final analysis of the two-year *BALANCE* study (the final Clinical Study Report), and an interim analysis of the long-term, open-label extension study of PRX-102 in adult patients with Fabry disease treated with the 2 mg/kg every four weeks dosage.

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

In December 2017, the European Commission granted Orphan Drug Designation for PRX-102 for the treatment of Fabry disease. Orphan Drug Designation for PRX-102 qualifies Chiesi for access to a centralized marketing authorization procedure, including applications for inspections and for protocol assistance. If the orphan drug designation is maintained at the time PRX-102 is approved for marketing in the European Union, if at all, we expect that PRX-102 will benefit from 10 years of market exclusivity within the European Union. The market exclusivity will not have any effect on Fabry disease treatments already approved at that time.

Key Trials and Design

Our clinical development program is designed to show that PRX-102 has a potential clinical benefit in adult Fabry patient populations when compared to currently 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. Providing a meaningful improvement in the health and quality of life for Fabry patients being treated with PRX-102 represents a significant potential market opportunity.

Our phase III clinical program of PRX-102 for the treatment of Fabry disease includes three individual studies; the *BALANCE* study, the *BRIDGE* study and the *BRIGHT* study, all of which have been completed. In 2015, we completed a phase I/II clinical trial of PRX-102, which was a dose range study in ERT-naïve adult Fabry patients. In the phase III clinical program, we are studying two potential dosing regimens for PRX-102; 1 mg/kg every two weeks, with the potential for improved efficacy and safety, offering an

alternative to existing enzyme replacement therapies, and 2 mg/kg every four weeks, which has the potential to lower treatment burden versus existing treatments and provide a better quality of life for Fabry patients.

Patients that completed the *BALANCE*, *BRIDGE* and *BRIGHT* studies, and the extension of the phase I/II study, were offered the opportunity to continue PRX-102 treatment in one of two long-term open-label extension studies. Currently, 126 subjects that participated in our PRX-102 clinical program have opted, with the advice of the treating physician, to continue PRX-102 treatment in one of our long-term, open label, extension studies. Such extension studies include 97 patients in the 1 mg/kg every two weeks extension study (PB-102-F60) with a total cumulative exposure of approximately 400 patient years (10 subjects that completed an extension study from the phase I/II study, 18 subjects that completed the *BRIDGE* study; and 69 subjects that completed the *BALANCE* study), and 29 subjects that completed the *BRIGHT* study in the 2 mg/kg every four weeks extension study (PB-102-F51) with a total cumulative exposure of approximately 110 patient years. Two of such subjects are being treated with 1 mg/kg every two weeks.

In February 2020, we, together with Chiesi, announced an agreement with the FDA for the Initial Pediatric Study Plan (iPSP) for PRX-102. The joint announcement was made after completion of discussions with the FDA and receipt of confirmation from the FDA in an official "Agreement Letter" which outlines an agreed-upon approach to evaluate the safety and efficacy of PRX-102 in pediatric Fabry patients in a clinical trial to be performed by Chiesi with our collaborative efforts.

Phase III BALANCE Study

The pivotal *BALANCE* study was a 24-month, randomized, double blind, active control study of PRX-102 in adult Fabry patients with deteriorating renal function that was designed to evaluate the safety and efficacy of 1 mg/kg of PRX-102 administered every two weeks compared to agalsidase beta (Fabrazyme). The last patient received the last treatment in this study in October 2021, and topline results from the study were announced in April 2022. The Clinical Study Report for the *BALANCE* study has since been completed (July 2022), and the final analysis confirmed the positive topline results and favorable tolerability profile. A total of 78 patients who were previously treated with agalsidase beta for at least one year with an estimated glomerular filtration rate (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.

The primary endpoint of the *BALANCE* study is the comparison in the annualized rate of decline of eGFR slope between the agalsidase beta and PRX-102 treatment arms. eGFR is considered a reliable and accepted test to measure kidney function and stage of kidney disease. Additional parameters evaluated include: cardiac assessment, Lyso-Gb_3 (a biomarker for monitoring Fabry patients during therapy), pain, quality of life, immunogenicity, Fabry Clinical Events, pharmacokinetics and other parameters.

As part of the September 2021 Type A End-of-Review meeting, the FDA, in principle, agreed that the proposed analysis of the *BALANCE* study demonstrating non-inferiority to agalsidase beta to be included in the data package for the PRX-102 BLA resubmission has the potential to support the approval of PRX-102 for the treatment of Fabry disease. Given the changed regulatory landscape in the United States with the full approval of agalsidase beta in March 2021 based on clinical endpoints, the primary analysis of the *BALANCE* study was changed from superiority to non-inferiority, as demonstrating superiority is no longer required under FDA guidelines. The primary endpoint of the *BALANCE* study compared the eGFR annualized changes (slope) between the two treatment arms in the intent-to-treat (ITT) analysis set (77 patients). The study met its pre-specified primary endpoint and demonstrated that PRX-102 was statistically non-inferior to agalsidase beta.

The median (95% confidence interval) of the eGFR slope in the PRX-102 arm was -2.514 mL/min/1.73 m^2/year (-3.788, -1.240) and -2.155 mL/min/1.73 m^2/year (-3.805, -0.505) in the agalsidase beta arm, demonstrating a large overlap in the confidence intervals of the two arms. The difference in medians (95% confidence interval) is -0.359 mL/min/1.73 m^2/year (-2.444, 1.726). The prespecified non-inferiority margin was met. The final results of the per-protocol analysis set (72 patients) are consistent with the ITT results, with an even smaller difference in medians (95% confidence interval); -0.118 mL/min/1.73 m^2/year (-2.450, 2.213). Additional sensitivity and supportive analyses investigated mean eGFR slopes using other statistical models. These models yielded results similar to the primary analysis and confirming non-inferiority of PRX-102 to agalsidase beta. These results supported the robustness of the methodology used for comparisons of treatment effects in the *BALANCE* study.

The study population (ITT analysis set) was composed of 47 males (61.0%) and 30 females (39.0%), with a mean (range) age of 44.3 (18-60) years. The mean duration of prior treatment with agalsidase beta was approximately six years. At baseline, mean (SD) eGFR was 73.69 ml/min/1.73m^2 (20.32) and median eGFR was 74.51 ml/min/1.73m^2; mean (SD) eGFR slope was -8.10 mL/min/1.73 m^2/year (5.92) and median eGFR slope was -7.25 ml/min/1.73m^2/year.

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 is 572.36 events for the PRX-102 arm and 816.85 events for the agalsidase beta arm.

Treatment-related adverse events 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.

Of the patients that completed the trial from both the PRX-102 and agalsidase beta treatment arms, 69 have opted, with the advice of the treating physician, to receive PRX-102 1 mg/kg every two weeks in the long-term open-label extension study (PB-102-F60, NCT03566017).

The planned data package for the BLA resubmission, given the changed regulatory landscape in the United States, will include the final two-year analyses of the *BALANCE* study.

Phase III BRIDGE Study

The *BRIDGE* study was a 12-month open-label, single arm switch-over study evaluating the safety and efficacy of pegunigalsidase alfa, 1 mg/kg infused every two weeks, in up to 22 Fabry patients previously treated with agalsidase alfa (Replagal; marketed by Takeda Pharmaceutical Company Limited (acquired Shire Plc)) for at least two years and on a stable dose for at least six months. The trial was completed in December 2019. 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. Eighteen of the patients who completed the study opted to roll over to a long-term extension study and continue to be treated with PRX-102. In the study, the mean annualized eGFR slope of the study participants improved from -5.90 mL/min/1.73m^2/year while on agalsidase alfa to -1.19 mL/min/1.73m^2/year on PRX-102 in all patients. Male patients improved from -6.36 mL/min/1.73m^2/year to -1.73 mL/min/1.73m^2/year and female patients improved from -5.03 mL/min/1.73m^2/year to -0.21 mL/min/1.73m^2/year. Following the switch to PRX-102, there was a decrease in patients with progressing or fast progressing kidney disease 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. Of the 22 patients enrolled in the *BRIDGE* study, 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.

Baseline characteristics of the 20 patients that completed the study, ranging from ages 28 to 60 years, were as follows: mean eGFR 75.87 mL/min/1.73m^2 in males, and 86.14 mL/min/1.73m^2 in females and plasma lyso-Gb_3 were 51.81 nM and 13.81 nM in males and females, respectively. While lyso-Gb_3 levels remain slightly high, particularly within the male cohort, continuous reduction in lyso-Gb_3 levels was observed of 19.55 nM (32.35%) in males and 4.57 nM (29.81%) in females.

Of the patients that completed the trial, 18 have opted, with the advice of the treating physician, to continue receiving PRX-102 1 mg/kg every two weeks in a long-term open-label extension study (PB-102-F60, NCT03566017).

Phase III BRIGHT Study

The *BRIGHT* study 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 trial, which was completed in June 2020, enrolled 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 Lyso-Gb_3, as well as other parameters. In addition, participating patients were evaluated to assess the safety and tolerability of PRX-102.

We announced final results from the *BRIGHT* study in March 2022. The results 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 pegunigalsidase alfa, 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 pegunigalsidase alfa every two weeks per protocol at the 11th infusion. One patient withdrew from the study after the first infusion due to a traffic accident.

First infusions of PRX-102 were administered under controlled conditions at the investigation site. Based on the protocol-specified criteria, patients were able to receive their PRX-102 infusions at a home care setup once the Investigator and Sponsor Medical Monitor agreed that it was safe to do so. Safety and efficacy exploratory endpoints were assessed throughout the 52-week study.

Overall, 33 of 183 total treatment-emergent adverse events (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 lead 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/1.73m^2/year indicating stability.

The study suggests that Fabry patients who are currently receiving ERT every 2 weeks may be successfully transitioned to PRX-102 2 mg/kg every four weeks as an effective and tolerable alternative treatment option. Additional long term data is being collected as part of the ongoing long term extension study (PB-102-F51, NCT03614234) of the 2 mg/kg PRX-102 every four weeks dose.

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.

COVID-19 Impact on PRX-102 Clinical Trials

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

Phase I/II Study

Our phase I/II clinical trial of PRX-102, which we completed in 2015, was a worldwide, multi-center, open-label, dose ranging study designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and efficacy parameters of PRX-102 in adult patients with Fabry disease. Sixteen adult, naïve Fabry patients (9 male and 7 female) completed the trial, each in one of three dosing groups, 0.2 mg/kg, 1 mg/kg and 2 mg/kg. Each patient received IV infusions of PRX-102 every two weeks for 12 weeks, with efficacy follow-up after six-month and twelve-month periods. A majority of the patients who completed the trial opted to continue receiving PRX-102 in an open-label, 60-month extension study under which all patients were switched to receive 1 mg/kg of the drug, the selected dose for our *BALANCE* and *BRIDGE* studies.

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

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

Results show that Lyso-Gb_3 levels decreased approximately 90% from baseline. Renal function remained stable with mean 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.

Commercialization Agreements with Chiesi Farmaceutici

We have entered into two exclusive global licensing and supply agreements for PRX-102 for the treatment of Fabry disease with Chiesi. The agreements have significant revenue potential for Protalix. Under the agreements, Protalix Ltd. has received $50.0 million in upfront payments and was entitled to development cost reimbursements of up to $45 million, up to more than $1.0 billion in potential milestone payments and tiered royalties of 15% - 35% (ex-US) and 15% - 40% (US).

On October 19, 2017, Protalix Ltd. and Chiesi entered into the Chiesi Ex-US Agreement pursuant to which Chiesi was granted an exclusive license for all markets outside of the United States to commercialize PRX-102. Under the Chiesi Ex-US Agreement, Chiesi made an upfront payment to Protalix Ltd. of $25.0 million in connection with the execution of the agreement, and Protalix Ltd. was entitled to additional payments of up to $25.0 million in development costs in the aggregate, capped at $10.0 million per year. Protalix Ltd. is also eligible to receive additional payments of up to a maximum of $320.0 million in regulatory and commercial milestone payments. Protalix Ltd. agreed to manufacture all of the PRX-102 needed for all purposes under the agreement, subject to certain exceptions, and Chiesi will purchase PRX-102 from Protalix Ltd., subject to certain terms and conditions. Chiesi is required to make tiered payments of 15% to 35% of its net sales, depending on the amount of annual sales, as consideration for the supply of PRX-102.

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

On May 13, 2021, we signed a binding term sheet with Chiesi pursuant to which we and Chiesi amended 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.

On August 29, 2022, we entered into the F/F Agreement and the Letter Agreement. 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 F/F Agreement shall continue in force until December 31, 2025, unless terminated earlier in accordance with the terms of the F/F Agreement and the term may be extended by mutual agreement for an additional period of seven years upon mutual written agreement prior to expiration of the initial term. The Letter Agreement changes the obligations of both us and Chiesi under the License 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 amends certain provisions of the License Agreements to reflect the appointment of Chiesi as a supplier of commercial fill/finish services and the potential establishment of an initial alternate source of commercial fill/finish services.

Elelyso® for the Treatment of Gaucher Disease

Elelyso (taliglucerase alfa), our first commercial product, was approved by the FDA in 2012 for injection as an enzyme replacement therapy (ERT) for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. In August 2014, the FDA approved Elelyso for injection for pediatric patients. Elelyso is the first plant cell derived recombinant protein to be approved by the FDA for the treatment of Gaucher disease and is now approved in over 20 markets.

Gaucher disease, also known as glucocerebrosidase, or GCD, deficiency, is a rare genetic autosomal recessive disorder and one of the most common Lysosomal Storage Disorders, or 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 and 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, is forecasted to be approximately $1.5 billion and $1.6 billion in 2021 and 2022, respectively, and to grow at a CAGR of approximately 8.6% from 2020-2027.

Commercialization Agreements for Elelyso

We have licensed to Pfizer the global rights to Elelyso in all markets excluding Brazil. Pfizer retains 100% of revenue and reimburses 100% of direct costs. We manufacture drug substance for Pfizer, subject to certain terms and conditions.

For the first 10-year period after the execution of our Amended Pfizer Agreement, we have agreed to sell drug substance to Pfizer for the production of Elelyso, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods subject to certain terms and conditions. In a subsequent amendment, we agreed that after the completion of the first 10-year supply period, the supply term would automatically extend for a five-year period.

We maintain distribution rights to Elelyso in Brazil through a supply and technology transfer agreement with Fiocruz, an arm of the Brazilian MoH.

Alidornase Alfa (PRX-110)

Alidornase alfa is our chemically-modified plant cell expressed recombinant human DNase I, administered via inhalation. Recombinant human DNase I enzymatically cleaves DNA but its activity is inhibited by actin, which is present in the blood and other target organs. PRX-110 is designed to be less susceptible to actin inhibition and have higher affinity to DNA, thus enhancing enzymatic activity. In-vitro studies have shown PRX-110 to have a highly improved catalytic efficiency and affinity to DNA, compared to dornase alfa (Pulmozyme®, currently the only commercially available DNase therapy), even more so in the presence of actin. We are continuing to evaluate potential strategic marketing partnerships and collaboration programs with biotechnology and pharmaceutical companies for this product candidate for various respiratory indications.

Uricase (PRX-115)

PRX-115 is our plant cell-expressed recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme under development for the potential treatment of severe gout. Gout is the most common inflammatory arthritis in the United States, affecting an estimated 9.2 million adults. Gout is caused by factors that elevate serum uric acid, or sUA, levels, which may include diet or genetic predisposition and environmental factors leading to hyperuricemia and tissue deposition of monosodium urate crystals, tophi, in joints and soft tissues, causing acute and chronic inflammation, and is characterized by recurrent flares. Gout flares lead to substantial morbidity by causing severe pain, reduced quality of life, decreased physical function, increased healthcare costs, and lost economic productivity. Furthermore, gout is strongly associated with metabolic syndromes, and may contribute to myocardial infarction, type 2 diabetes mellitus, chronic kidney disease, or CKD, and premature mortality.

Severe gout is generally described as a state of gout in which there is a presence of monosodium urate crystals with any of the following: frequent recurrent gout flares, chronic gouty arthritis, subcutaneous tophi or disease elements of gout seen via imaging. It is estimated that approximately 2-5% of the gout population is considered to have chronic refractory disease, and we believe the frequency of severe gout is even higher.

Currently available urate-lowering therapies, or ULTs, can be effective in treating gout. However, we believe that new effective, safe therapies are needed to treat severe gout and chronic refractory gout regardless of treatment history. One treatment option may be a therapeutic use of the uricase enzyme which converts uric acid to allantoin, which is easily eliminated through urine. The uricase enzyme does not exist naturally in humans. To date, two variants of recombinant uricases are approved for marketing: (i) Krystexxa® (pegloticase) for treatment of chronic gout refractory to conventional therapy (gout patients that have contraindication/failure of other lowering uric acid treatments) and (ii) Elitek®, indicated for the treatment of tumor lysis syndrome but not gout. Both have a black box warning for anaphylaxis, induce strong immunogenic reactions and have other major side-effects. In particular, 89% of patients treated with Krystexxa developed an immunogenic response associated with a failure to maintain normalization of serum uric acid levels over a 6-month therapy cycle. In addition, a recent phase IV study demonstrates that co-treatment with Krystexxa and methotrexate increases efficacy and tolerability in patients with uncontrolled gout. Krystexxa is no longer marketed in the European Union for commercial reasons.

We use ProCellEx to express an optimized recombinant uricase enzyme under development for the potential treatment of severe gout which we are designing to lower uric acid levels while having low immunogenicity and increased half-life in the circulation. Pre-clinical data demonstrates stable PK profile and long half-life, low immunogenic risk and high specific activity supporting the potential of PRX-115 to be a safe and effective treatment for severe gout. Preliminary results of the first stage of one-month multiple dosing toxicity studies of PRX-115 in two species show no indication of safety concerns and our current development plan goal is to initiate a phase I clinical trial in the first quarter of 2023.

PRX-119

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

Intellectual Property

A key element of our overall strategy is to establish a broad portfolio of patents to protect our proprietary technology, proprietary product and product candidates and their methods of use. As of September 30, 2022, we hold a broad portfolio of over 80 patents in Europe, the United States, Israel and additional countries worldwide, as well as over 30 pending patent applications.

Scientific Presentations

The five poster presentations listed below were available at the 2022 Program: 7th Update on Fabry Disease: Biomarkers, Progression and Treatment Opportunities. The program was supported by Kidneys for Life, a Registered UK Charitable Organization (Manchester, UK), and took place May 29, 2022 through May 31, 2022.

The four poster presentations listed below were available at the Society for the Study of Inborn Errors of Metabolism (SSIEM) 2022 Annual Symposium held from August 30, 2022 through September 2, 2022 in Freiburg, Germany.

Switching from Agalsidase Alfa to Pegunigalsidase Alfa to Treat Patients with Fabry Disease: 1 Year of Treatment Data from BRIDGE, a Phase 3 Open-label Study

Safety and Efficacy of Pegunigalsidase Alfa Administered Every 4 Weeks in Patients with Fabry Disease: Results from the Phase 3 Open-label, BRIGHT Study

Tolerability and Infusion Duration (ID) of Pegunigalsidase Alfa (PA) in Patients (pts) with Fabry Disease (FD): Data from 5 Completed Clinical Trials

Long-term Safety and Efficacy of Pegunigalsidase Alfa: a Multicenter Extension Study in Adult Patients with Fabry Disease

Research & Development

We continuously work on the further development of our ProCellEx plant cell expression technology and bioreactor system. In addition, we are working on the development of new products, each in different initial stages of development, for specific products for which there are unmet needs in terms of efficacy and safety. Our development strategy focuses on the utilization of different modification approaches and development improvements, customized for each protein product, in all stages of expression and development.

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, 2021.

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

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

Results of Operations

Three months ended September 30, 2022 compared to the three months ended September 30, 2021

Revenues from Selling Goods

We recorded revenues from selling goods of $8.8 million during the three months ended September 30, 2022, an increase of $4.3 million, or 96%, compared to revenues of $4.5 million for the three months ended September 30, 2021. An increase of $3.4 million in sales to Pfizer, resulting from timing differences, and an increase of $2.4 million in sales to Chiesi was partially offset by a decrease of $1.5 million in sales to Brazil resulting from timing differences.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $5.4 million for the three months ended September 30, 2022, a decrease of $2.1 million, or 28%, compared to revenues of $7.5 million for the three months ended September 30, 2021. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements.

Cost of Goods Sold

Cost of goods sold was $7.1 million for the three months ended September 30, 2022, an increase of $3.4 million, or 91%, from cost of goods sold of $3.7 million for the three months ended September 30, 2021. The increase in cost of goods sold was primarily the result of the increase in sales of goods.

Research and Development Expenses

For the three months ended September 30, 2022, our total research and development expenses were approximately $7.4 million comprised of approximately $4.9 million in subcontractor-related expenses, approximately $1.7 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.6 million of other expenses. For the three months ended September 30, 2021, our total research and development expenses were approximately $7.3 million comprised of approximately $4.8 million in subcontractor-related expenses, approximately $1.6 million of salary and related expenses, approximately $0.1 million of materials-related expenses and approximately $0.8 million of other expenses.

Total increase in research and developments expenses was $0.1 million, or 1%, for the three months ended September 30, 2022 compared to the three months ended September 30, 2021.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.8 million for the three months ended September 30, 2022, a decrease of $0.2 million, or 7%, compared to $3.0 million for the three months ended September 30, 2021. The decrease was primarily due to a decrease in salary-related and selling costs.

Financial Expenses, Net

Financial expenses, net were $0.4 million for the three months ended September 30, 2022, compared to financial expenses, net of $2.3 million for the three months ended September 30, 2021. The decrease resulted primarily from lower interest and debt amortization costs due to a decrease in our outstanding notes from an aggregate principal amount of $57.92 million of 2021 Notes to an aggregate principal amount of $28.75 million of 2024 Notes, and an increase in the exchange rate of New Israeli Shekels for U.S. Dollars over the period.

Nine months ended September 30, 2022 compared to the nine months ended September 30, 2021

Revenues from Selling Goods

We recorded revenues from selling goods of $21.2 million during the nine months ended September 30, 2022, an increase of $8.9 million, or 72%, compared to revenues of $12.3 million for the nine months ended September 30, 2021. The increase resulted from an increase of $3.4 million in sales to Pfizer, an increase of $2.9 million in sales to Brazil and an increase of $2.6 million in sales to Chiesi.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $17.8 million for the nine months ended September 30, 2022, an increase of $0.3 million, or 2%, compared to revenues of $17.5 million for the nine months ended September 30, 2021. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements.

Cost of Goods Sold

Cost of goods sold was $17.2 million for the nine months ended September 30, 2022, an increase of $4.0 million, or 30%, from cost of goods sold of $13.2 million for the nine months ended September 30, 2021. The increase in cost of goods sold was primarily the result of the increase in sales of goods.

Research and Development Expenses

For the nine months ended September 30, 2022, our total research and development expenses were approximately $23.7 million comprised of approximately $15.1 million in subcontractor-related expenses, approximately $5.4 million of salary and related expenses, approximately $1.2 million of materials-related expenses and approximately $2.0 million of other expenses. For the nine months ended September 30, 2021, our total research and development expenses were approximately $22.1 million comprised of approximately $14.1 million in subcontractor-related expenses, approximately $5.3 million of salary and related expenses, approximately $0.5 million of materials-related expenses and approximately $2.2 million of other expenses.

The increase in research and developments expenses of $1.6 million, or 7%, from the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021 resulted primarily from a $1.0 million increase in subcontractor-related expenses in connection with regulatory submissions for PRX-102, and a $0.7 million increase in materials-related expenses.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $8.6 million for the nine months ended September 30, 2022, a decrease of $0.7 million, or 8%, compared to $9.3 million for the nine months ended September 30, 2021. The decrease resulted primarily from a decrease in professional fees and salary-related expenses.

Financial Expenses, Net

Financial expenses, net were $0.7 million for the nine months ended September 30, 2022, a decrease of $5.5 million, or 89%, compared to $6.2 million for the nine months ended September 30, 2021. The decrease resulted primarily from lower interest and debt amortization costs due to a decrease in our outstanding notes from an aggregate principal amount of $57.92 million of 2021 Notes to an aggregate principal amount of $28.75 million of 2024 Notes, and an increase in the exchange rate of New Israeli Shekels for U.S. Dollars over the period.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and bank deposits. At September 30, 2022, we had $20.8 million in cash and cash equivalents and short term bank deposits. We have primarily financed our operations through equity and debt financings, business collaborations, and grants funding.

During the year ended December 31, 2021, we raised gross proceeds equal to approximately $8.8 million from sales of common stock under our ATM program through the sale of 1,867,552 shares of our common stock. In addition, we raised gross proceeds of

approximately $40.2 million from a public offering of our common stock before deducting the underwriting discount and estimated expenses of the offering. In connection with the offering, we issued 8,749,999 shares of our common stock at a purchase price per share of $4.60. During the nine months ended September 30, 2022, we raised gross proceeds equal to approximately $4.4 million from sales of common stock under our ATM program through the sale of 3,841,479 shares of our common stock.

On August 25, 2021, we completed exchanges, or the Exchanges, of a substantial majority of our then outstanding 7.50% Senior Secured Convertible Notes due 2021, or the 2021 Notes, with institutional note holders of a substantial majority of the 2021 Notes. The Exchanges involved the exchange of an aggregate of $54.65 million principal amount of our 2021 Notes for an aggregate of $28.75 million principal amount of newly issued 7.50% Senior Secured Convertible Notes due 2024, or the 2024 Notes, $25.90 million in cash, and approximately $1.1 million in cash representing accrued and unpaid interest through the closing date. The initial conversion rate for the 2024 Notes is 563.2216 shares of our common stock for each $1,000 principal amount of 2024 Notes (equivalent to an initial conversion price of approximately $1.7755 per share of common Stock, subject to adjustment in certain circumstances. This initial conversion price represents a premium of approximately 32.5% relative to the closing price of the common stock on the NYSE American on August 13, 2021. After giving effect to the Exchanges, $3.27 million aggregate principal amount of the 2021 Notes remained outstanding. On November 15, 2021, all of the then outstanding 2021 Notes matured and were paid in full.

The 2024 Notes were issued pursuant to the Indenture dated as of August 24, 2021 between us, the guarantors party thereto, The Bank of New York Mellon Trust Company, N.A., as trustee and Wilmington Savings Fund Society, FSB, as collateral agent, or the 2024 Indenture. Interest on the Notes are payable semi-annually at a rate of 7.50% per annum. The 2024 Notes will mature on September 1, 2024, unless earlier purchased, converted, exchanged or redeemed, and are guaranteed by our subsidiaries. The 2024 Notes are secured by perfected liens on all of our assets, including those of our subsidiaries. Under the terms of the 2024 Indenture, we are required to comply with certain covenants, including the requirement to maintain a minimum cash balance of at least $7.5 million. Failure to comply with such covenants may result in an event of default under the 2024 Indenture and, accordingly, may result in the acceleration of the payment of the notes or in additional interest payments. As of September 30, 2022, we were in compliance with all covenants.

We believe that our cash and cash equivalents and short-term bank deposits as of September 30, 2022 are sufficient to satisfy our capital needs for at least 12 months from the date that these financial statements are issued.

Cash Flows

Net cash used in operations was $22.4 million for the nine months ended September 30, 2022. The net loss for the nine months ended September 30, 2022 of $11.2 million was increased by a $5.5 million decrease in contracts liability, a $4.4 million decrease in accounts payable and accruals, a $5.7 million increase in accounts receivable and other assets and an increase of $1.1 million in financial income, net (mainly exchange differences), and was partially offset by a $3.4 million decrease in inventories and $1.5 million in share-based compensation. Net cash used in investing activities for the nine months ended September 30, 2022 was $10.0 million and consisted primarily of net investment in bank deposits. Net cash provided by financing activities was $4.2 million resulting primarily from the sale of common stock under our ATM program.

Net cash used in operations was $5.2 million for the nine months ended September 30, 2021. In response to the COVID-19 pandemic, a higher number of subjects in our ongoing clinical trials opted for home care treatments over in-site treatments which resulted in an immaterial amount of additional expenses. The net loss for the nine months ended September 30, 2021 of $20.9 million was increased by a $4.1 million increase in accounts receivable and other assets and a $1.6 million increase in inventories, and was partially offset by a $13.9 million increase in contracts liability, a $2.6 million of amortization of debt issuance costs and debt discount, $2.0 million in share-based compensation and a $1.1 million increase in accounts payable and accruals. Net cash used in investing activities for the nine months ended September 30, 2021 was $18.5 million and consisted primarily of a net increase in bank deposits. Net cash provided by financing activities was $16.1 million resulting from the sale of common stock under our former ATM program and from our public offering of common stock, net of the convertible notes and promissory note payments.

Future Funding Requirements

We expect to continue to incur significant expenditures in the near future as we increase our research and developments efforts with respect to our product candidates given the receipt of the CRL from the FDA discussed above, we expect to incur additional expenses in connection with any resubmission. We cannot anticipate the costs or the timing of the occurrence of such costs. In addition, to the extent we need to obtain additional financing in connection with this process or with any additional clinical testing that may be required, it may be more difficult for us to do so given the volatility of the price of our common stock. Our material cash needs for the next 24 months will include, among other expenses, (i) costs of preclinical and clinical trials, (ii) employee salaries, (iii) payments for rent and operation of our manufacturing facilities, (iv) fees to our consultants and legal advisors, patent advisors and fees for service providers in connection with our research and development efforts and (v) payment of interest on our outstanding 2024 Notes. 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.

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

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

We expect to finance our future cash needs through corporate collaborations, licensing or similar arrangements, public or private equity offerings and/or debt financings. We currently do not have any commitments for future external funding, except with respect to the development-related payments and milestone payments that may become payable under the Chiesi Agreements. On July 2, 2021, we entered into the Sales Agreement in connection with a new ATM program, as amended on May 2, 2022, pursuant to which we may sell from time to time through the Agent ATM Shares having an aggregate offering price of up to $20.0 million. On the same date, we terminated our former ATM program. As of September 30, 2022, shares of Common Stock for total gross proceeds of approximately $15.6 million remain available to be sold under the Sales Agreement.

Effects of Currency Fluctuations

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services and salaries expenses. Currency fluctuations during the nine months ended September 30, 2022 resulted in $1.0 million recognized as a financial income. We do not believe currency fluctuations have had a material effect on our results of operations during the nine months ended September 30, 2021.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2022 and December 31, 2021.

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 approximately 65% of our expenses and capital expenditures, as well as the repayment of our 2021 Notes in 2021, 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 31% 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:

	September 30,		December 31,
	2022	2021	2021
Average rate for period	3.315	3.255	3.230
Rate at period-end	3.543	3.229	3.110

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

Interest Rate Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Inherent Limitations on Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended September 30, 2022 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

Except as set forth below, there have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021 and in our Quarterly Reports for the three-month periods ended March 31, 2022 and June 30, 2022.

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

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

Additionally, on September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The U.S. Department of Health and Human Services, or the HHS, plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or the IRA, in August 2022, which will, among other things, allows HHS to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least seven years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed or Furnished Herewith
		Form	File Number	Exhibit	Date	
3.1	Certificate of Incorporation of the Company	8-K	001-33357	3.1	April 1, 2016	
3.2	Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	July 1, 2016	
3.3	Second Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	October 17, 2018	
3.4	Third Amendment to Certificate of Incorporation of the Company	8-K	001-33357	3.1	December 19, 2019	
3.5	Fourth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.5	August 15, 2022	
3.6	Bylaws of the Company	8-K	001-33357	3.2	April 1, 2016	
4.1	Form of Restricted Stock Agreement/Notice	8-K	001-33357	4.1	July 18, 2012	
4.2	Description of Capital Stock	10-K	001-33357	4.7	March 12, 2020	
4.3	Form of Warrant	8-K	001-33357	4.1	March 12, 2020	
4.4†	Form of Stock Option Agreement (Executives)	10-Q	001-33357	4.8	August 10, 2020	
4.5	Form of Stock Option Agreement (Standard)	10-Q	001-33357	4.9	August 10, 2020	
4.6	Indenture, dated as of August 24, 2021, between Protalix BioTherapeutics, Inc., the guarantors party thereto, The Bank of New York Mellon Trust Company, N.A., as trustee and Wilmington Savings Fund Society, FSB, as collateral agent	8-K	001-33357	4.2	August 26, 2021	
4.7	Form of Exchange Note (2024)	8-K	001-33357	4.3	August 26, 2021	
10.1††	Fill/Finish Agreement effective on August 29, 2022 made by and between Chiesi Farmaceutici S.p.A and Protalix Ltd.					X
10.2††	Letter Agreement dated August 29, 2022 from Chiesi Farmaceutici S.p.A to Protalix Ltd.					X
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X
32.1	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer					X
32.2	18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer					X
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X

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

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

†† The registrant has omitted portions of the exhibit as permitted under Item 601(b)(10) of Regulation S-K. The registrant agrees to furnish supplementally a copy of the omitted schedules and exhibits to the SEC upon request.

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 14, 2022

By: /s/ Dror Bashan

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

Date: November 14, 2022

By: /s/ Eyal Rubin

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

Exhibit 10.1

CONFIDENTIAL *EXECUTION VERSION*

Certain confidential portions of this exhibit have been omitted and replaced with "[***]". Such identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

FILL/FINISH AGREEMENT

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by and between

CHIESI FARMACEUTICI S.p.A.

and

PROTALIX LTD.

FILL/FINISH AGREEMENT

THIS FILL/FINISH AGREEMENT (this "Agreement") is effective on August 29, 2022, and is made by and between:

1. **CHIESI FARMACEUTICI S.p.A**., a company incorporated under the laws of Italy with offices located at Via Palermo 26/A Parma, 43122 Italy ("Chiesi" or "Supplier"); and

2. **PROTALIX LTD.**, a limited liability company incorporated under the laws of Israel with offices located at 2 Snunit Street, Science Park, P.O. Box 455, Karmiel 2161401, Israel ("Protalix" or "Customer").

WHEREAS:

(A) Protalix is the owner of or has been granted the Intellectual Property Rights pertaining to the Drug Substance, Drug Product and Licensed Product (as used throughout herein, as defined in the applicable License Agreement);

(B) Protalix and Chiesi are parties to (i) that certain Exclusive License and Supply Agreement dated October 17, 2017; and (ii) that certain Exclusive U.S. License and Supply Agreement dated July 23, 2018 ((i) and (ii), collectively, the "License Agreements," and each, a "License Agreement"), pursuant to which Protalix granted to Chiesi, among other rights, an exclusive license to certain Intellectual Property Rights with respect to the commercialization of the Licensed Product worldwide;

(C) Protalix now desires to conduct a technology transfer of the Fill/Finish manufacturing process, including a technology transfer of analytical methods, for Drug Product to Chiesi and purchase the Fill/Finish supply services for Drug Product from Chiesi hereunder;

(D) Chiesi now desires to receive such technology transfer of the Fill/Finish manufacturing process for Drug Product and perform Fill/Finish supply services for Protalix with respect to: (i) the commercial supply of the Drug Product; (ii) the conduct of any Extension Studies (as defined in the applicable License Agreement) in accordance with the License Agreements; and (iii) otherwise in connection with exploratory development and lifecycle extensions for the Drug Product; and

(E) The Parties have agreed to enter into this Agreement to set forth the terms and conditions on which the Parties will conduct the technology transfer of the Fill/Finish manufacturing process to Chiesi, Supplier will so conduct the Fill/Finish activities, and Customer will supply to Supplier the Drug Substance in connection therewith.

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

1. **DEFINITIONS**

Certain capitalized terms used herein but not defined below are defined elsewhere in the Agreement. Unless otherwise specifically provided in this Agreement, the following terms shall have the meanings set forth below.

1.1 "Acceleration Date" has the meaning set forth in Exhibit 1.

1.2 "Agreement" has the meaning set forth in the preamble.

1.3 "Affiliate" means any entity directly or indirectly controlled by, controlling, or under common control with, a Party to this Agreement, but only for so long as such control shall continue. For purposes of this definition, "control" (including, with correlative meanings, "controlled by", "controlling" and "under common control with") means (a) possession, direct or indirect, of the power to direct or cause direction of the

management or policies of an entity (whether through ownership of securities or other ownership interests, by contract or otherwise), or (b) beneficial ownership of at least fifty-percent (50%) of the voting securities or other ownership interest (whether directly or pursuant to any option, warrant or other similar arrangement) or other comparable equity interests of an entity, it being understood and agreed that for purposes of clause (a), neither ownership of voting securities or other ownership interests of an entity nor membership or representation on (if less than half of the members of) an entity's board of directors shall, by themselves, be presumed to constitute the power to direct or cause direction of the management or policies of such entity.

1.4 "Applicable 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, in any country or jurisdiction that are applicable to the conduct of Fill/Finish activities in respect of the Drug Substance and Drug Product, or to a Party's performance of its obligations hereunder.

1.5 "Applicable Standards" means good practice requirements and guidelines of any country or jurisdiction applicable to a Party's performance of its respective obligations hereunder, including, but not limited to, cGMP.

1.6 "Background Intellectual Property" has the meaning set forth in Section 20.1.

1.7 "[***]" has the meaning set forth in Section 17.7(c).

1.8 "Bulk Drug Product" means unlabeled vials of Licensed Product that have been filled and crimped, but have not completed the testing contemplated by clause (b) of the definition of "Fill/Finish".

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

1.10 "cGMP" means all applicable good manufacturing practices including, (a) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice, (b) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 600, 601 and 610, (c) EU Current Good Manufacturing Practice for Medicinal Products Eudralex Volume 4, (d) the principles detailed in the ICH Q7A guidelines, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.11 "Chiesi" and "Supplier" have the meaning set forth in the preamble.

1.12 "Claims" has the meaning set forth in Section 17.1.

1.13 "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, 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.

1.14 "Confidential Information" means all information or data of a proprietary or confidential nature regarding a Party's business, operations, products, services, technology, layout, and/or equipment, including, without limitation, business,

financial, technical, clinical and scientific information, whether in oral, written, graphic, machine-readable form, or any other form (provided that data and information disclosed orally or visually are confirmed in writing by the disclosing Party within thirty (30) days after the date of such disclosure), disclosed and/or made available by or on behalf of a Party to the other Party or its Affiliates, and its and their respective Representatives as a result of or in connection with this Agreement and/or the Parties' discussions pertaining to this Agreement (whether prior to the execution hereof or thereafter). Notwithstanding the foregoing, unmarked information and un-confirmed information will be considered Confidential Information under this Agreement if a reasonable person familiar with the Drug Substance and the Drug Product and given the nature of information and the circumstances of disclosure would consider such information to be confidential. Such information shall not be considered to be Confidential Information of a disclosing Party to the extent that such information is: (a) as of the date of disclosure known to the receiving Party or its Affiliates (other than pursuant to the License Agreement(s)) and free from any obligation of confidentiality, as demonstrable in any tangible medium in existence at the time of disclosure; or (b) wholly disclosed in published literature, or otherwise is or becomes generally known to the public through no breach by the receiving Party of this Agreement; or (c) obtained by the receiving Party or its Affiliates from a Third Party free from any obligation of confidentiality to the disclosing Party; or (d) independently developed by the receiving Party or its Affiliates without use of or reference or access to the disclosing Party's Confidential Information.

1.15 "Critical Regulatory Inspection Deficiency" has the meaning set forth in Section 13.11.

1.16 "Customer Indemnitees" has the meaning set forth in Section 17.1.

1.17 "Customer Intellectual Property" has the meaning set forth in Section 20.2.

1.18 "Damages" has the meaning set forth in Section 17.1.

1.19 "Dependency Event – Inspection Deficiency" has the meaning set forth in Section 13.12.

1.20 "Dependency Event" has the meaning set forth in Section 17.8.

1.21 "Dispute" has the meaning set forth in Section 19.2.

1.22 "Dispute Notice" has the meaning set forth in Section 19.2(a).

1.23 "Drug Product" means unlabeled vials of Licensed Product that have undergone Fill/Finish, but not Labeling and Packaging.

1.24 "Drug Substance" means the Compound (as defined in the applicable License Agreement) component of a pharmaceutical drug product.

1.25 "DS Cost" means, with respect to an applicable given quantity of Drug Substance hereunder, [***] and as determined in accordance with GAAP, consistently applied.

1.26 "[***]" has the meaning set forth in Section 17.7(c).

1.27 "DP Purchase Order" has the meaning set forth in Section 7.2.

1.28 "Effective Date" means the date indicated above.

1.29 "Excess DS Consumption" has the meaning set forth in Section 7.1.

1.30 "Fill/Finish" means the fill and finish, bulk packaging, testing and release of Drug Product to be performed by Supplier hereunder, including (a) filling the Drug Substance into vials and (b) testing, including in process release to Labeling and Packaging and ongoing stability testing of the Drug Product. For the avoidance of doubt, Fill/Finish shall not include any activities included in the definition of Labeling

and Packaging. When used as a verb, "Fill/Finish" means to conduct Fill/Finish, and "Fill/Finished" has a correlative meaning.

1.31 "Fill/Finish Licenses" means all licenses, permits, approvals, authorizations and consents necessary for, or required by Applicable Law to be maintained by Supplier for, its performance of Fill/Finish activities at its applicable facility(ies) hereunder.

1.32 "Force Majeure Event" has the meaning set forth in Section 21.1.

1.33 "Forecast" has the meaning set forth in Article 6.

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

1.35 "ICC Rules" has the meaning set forth in Section 19.2(b).

1.36 "Indemnified Party" has the meaning set forth in Section 17.4(a).

1.37 "Indemnifying Party" has the meaning set forth in Section 17.4(a).

1.38 "Initial Alternate Source" has the meaning set forth in Section 3.3.

1.39 "Intellectual Property Rights" means know-how, trade secrets, Patent Rights (as defined in the applicable License Agreement), trademarks, service marks, trade names, design rights, copyrights (including rights in computer software) and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights, and all rights or forms of protection having equivalent or similar effect, in any part of the world.

1.40 "June Forecast" has the meaning set forth in Article 6.

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

1.42 "License Agreement" and "License Agreements" have the meaning set forth in the recitals.

1.43 "Lost Drug Substance" has the meaning set forth in Section 9.4.

1.44 "Maintenance" or "Maintain" shall mean all necessary actions and works for retaining or restoring the applicable equipment, or pieces thereof, to carry on the operation of such equipment in proper condition and compensating for normal wear and tear or as agreed to in writing by the Parties.

1.45 "Materials" means any materials of any nature, except Drug Substance, that are used by, or are necessary for, Supplier to conduct Fill/Finish hereunder.

1.46 "Non-Conformance" has the meaning set forth in Section 10.1.

1.47 "OOS" means any non-conformance in relation to quality acceptance levels, defined from a regulatory point of view (e.g., pharmacopoeias, registration documents).

1.48 "Parties" means Customer (or Protalix) and Supplier (or Chiesi) (collectively), and "Party" means either Customer (or Protalix) and Supplier (or Chiesi), as the case may be.

1.49 "Processed Drug Substance" has the meaning set forth in Section 9.3.

1.50 "Product Requirements" means the written specifications for Drug Product, as specified in the written dossier for such Drug Product to be provided by Customer to Supplier as of the Effective Date in connection with the Tech Transfer Plan, as the same

may be updated from time to time in accordance with the QA, Section 5.3 or Section 21.4 of this Agreement.

1.51 "Product Schedule" means the written Drug Product schedule to this Agreement, entered into by and between the Parties (or any or their Affiliates) in accordance with Section 2.2 which sets forth the particulars for the Fill/Finish of Drug Product under this Agreement, including, all specifications (including, by form or dosage, as applicable), Materials and price for the Drug Product, and which is subject to amendment from time to time during the Term pursuant to Section 21.4 hereof.

1.52 "Protalix" and "Customer" have the meaning set forth in the preamble.

1.53 "Quality Agreement" or "QA" means, individually or collectively as applicable, QA1, QA2 and QA3.

1.54 "Quality Agreement 1" or "QA1" means that certain Amended & Restated Quality & Technical agreement dated February 28, 2022, by and between the Parties, that defines the regulatory case vis-à-vis Regulatory Authorities in connection with the supply of Drug Substance, the Fill/Finish of Drug Product hereunder and the certification of finished product, when Supplier is the sponsor of clinical trials or the manufacturing authorization holder (MAH), as such agreement may be amended from time to time. QA1 is attached as Exhibit 2.

1.55 "Quality Agreement 2" or "QA2" means the quality agreement to be entered into by the Parties (as contemplated in Section 5.1) that defines the regulatory case vis-à-vis Regulatory Authorities in connection with the supply of Drug Substance, the Fill/Finish of Drug Product hereunder, packaging for clinical trials and the certification of finished product when Customer is the sponsor of clinical trials, as such agreement may be amended from time to time.

1.56 "Quality Agreement 3" or "QA3" means the quality agreement to be entered into by the Parties (as contemplated in Section 5.1) that defines the quality roles and responsibilities of each Party in connection with the Fill/Finish of Drug Product hereunder, as such agreement may be amended from time to time.

1.57 "Recall" has the meaning set forth in Article 14.

1.58 "Regulatory Authority" means, in respect of a particular country or jurisdiction, the Governmental Authority having responsibility for granting Regulatory Approvals (as used throughout herein, as defined in the applicable License Agreement) in such country or jurisdiction.

1.59 "Regulatory Inspection Deficiency" has the meaning set forth in Section 13.10.

1.60 "Remaining Vials" has the meaning set forth in Exhibit 1.

1.61 "Representatives" means, with respect to a Party, such Party's Affiliates and its and their respective officers, directors, employees, authorized consultants, contractors, and agents.

1.62 "Shortage" has the meaning set forth in Section 8.4.

1.63 "Supplier Indemnitees" has the meaning set forth in Section 17.2.

1.64 "Supplier Intellectual Property" has the meaning set forth in Section 20.3.

1.65 "Tech Transfer" has the meaning set forth in Section 4.1.

1.66 "Tech Transfer Plan" has the meaning set forth in Section 4.1.

1.67 "Term" has the meaning set forth in Section 18.1.

1.68 "Theoretical Yield" means, with respect to each batch of Drug Substance supplied by Customer, [***].

1.69 "Third Party" means any person or entity other than Chiesi, Protalix, or any of their respective Affiliates.

1.70 "Third Party Claim" has the meaning set forth in Section 17.4(a).

1.71 "Third Party Product Claim" has the meaning set forth in Section 17.3.

1.72 "[***]" has the meaning set forth in Section 17.7(c).

1.73 "Triggering Event" has the meaning set forth in Section 2.4.

1.74 "[***]" has the meaning set forth in Exhibit 1.

2. **CONSTRUCTION**

2.1 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, law or instrument mean such agreement, law 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", or "Exhibit" refer to an Article or Section of, or any Exhibit to, this Agreement unless otherwise indicated; (f) the word "will" shall be construed to have the same meaning and effect as the word "shall"; (g) the word "any" shall mean "any and all" unless otherwise indicated by context; (h) the use of the word "or" has the inclusive meaning represented by the phrase "and/or"; and (i) references to "days" shall mean calendar days (unless Business Days are expressly specified), and references to "months" or "years" shall mean calendar months and calendar years, respectively. The wording of this Agreement shall be deemed to be the wording mutually chosen by the Parties and no rule of strict construction shall be applied against a Party. Except as otherwise specifically stated to the contrary in this Agreement, each Party shall bear its own costs of entering into and performing its obligations under this Agreement.

2.2 Specific terms and conditions for the Fill/Finish of designated Drug Products are set forth in the Product Schedule attached as Exhibit 1, and Product Schedules to be entered into by and between the Parties in the form that is substantially similar to Exhibit 1. Any number of Product Schedules may be executed pursuant to this Agreement during the Term.

2.3 The Exhibits and the Product Schedules form part of this Agreement and have the same force and effect as if expressly set out in the body of this Agreement. Any reference to this Agreement includes the Exhibits and the Product Schedules. Any breach of any Exhibit or Product Schedule shall be deemed as a breach of this Agreement.

2.4 The Parties acknowledge and agree that the execution and implementation of this Agreement does not constitute [***]. Solely to the extent that a Party's [***] (with respect to this Agreement, a "Triggering Event"), causes [***].

3. **SUPPLY OF DRUG PRODUCT**

3.1 During the Term, Customer hereby appoints Supplier to perform, and Supplier shall perform, the Fill/Finish and supply of Drug Product for Customer, including as described in Recital (D) above, and Customer shall purchase such Drug Product from Supplier, hereunder, in each case subject to and in accordance with the terms and conditions set forth herein (including the Product Schedules). For the avoidance of doubt, subject to Section 18.5(b)(iii) and Subsection 2(g) of Part B of Exhibit 1, this Agreement shall not be construed as a requirements contract, or as an exclusive contract, and shall not be interpreted to obligate Customer to purchase a minimum

volume of Drug Product from Supplier (except with respect to the Minimum Batch Size in any applicable License Agreement).

3.2 Supplier shall not subcontract Fill/Finish (or any portion thereof) to a Third Party without obtaining the prior written consent of Customer (such consent not to be unreasonably withheld, conditioned, or delayed). Each Party shall ensure that each of its Affiliates and permitted subcontractors accepts and complies with all of the applicable terms and conditions of this Agreement as if such Affiliates or permitted subcontractors were parties to this Agreement, and each Party shall remain fully responsible and fully liable for its Affiliates' and permitted subcontractors' performance under this Agreement.

3.3 Contemporaneously with the execution of this Agreement, the Parties have executed a side letter to the License Agreement with respect to establishing an alternative source for Fill/Finish (the "Initial Alternate Source").

4. TECHNOLOGY TRANSFER; EQUIPMENT

4.1 Customer shall transfer such technology and technical information to Supplier as is necessary and reasonably useful for the Fill/Finish and supply of Drug Product hereunder, including process development, process validation and process optimization and all applicable analytical methods and inspection procedures, to secure the establishment of Fill/Finish and quality control of the Drug Product at Supplier's manufacturing facilities (the "Tech Transfer") in accordance with the Tech Transfer Plan and this Agreement. The Parties shall, at Supplier's reasonable request, establish a joint project team, which shall discuss and propose updates and amendments to the Tech Transfer Plan for mutual written approval by the Parties (not to be unreasonably withheld, conditioned or delayed). "Tech Transfer Plan" means, collectively, the written technology transfer plan with respect to the [***] Drug Product mutually agreed by the Parties in writing and the written technology transfer plan with respect to the [***] Drug Product to be mutually agreed by the Parties in writing as soon as reasonably practicable after the Effective Date, which set out the details and activities for the Tech Transfer, including the time schedule, documentation, information, reports, costs, equipment, and technical assistance, as the same may be revised from time to time in accordance with this Agreement. The initial Tech Transfer Plan with respect to the [***] Drug Product is attached and incorporated as Exhibit 3, and any written amendments thereto signed by both Parties shall amend and modify the then-current Tech Transfer Plan and Exhibit 3 shall be updated accordingly. Upon [***] the initial Tech Transfer Plan with respect to the [***] Drug Product, Exhibit 3 shall be updated to incorporate such Tech Transfer Plan. After the completion of the Tech Transfer and the above activities, the joint project team will be dissolved and replaced with an Operational Team. The Parties shall allocate sufficient resources to perform the above activities. Customer shall remunerate Supplier for its reasonable activities and any start-up costs as agreed by the Parties in advance and in writing to the extent provided in Section 5 of Part B of Exhibit 1. Supplier may not use Customer's technology for any purpose other than the Fill/Finish hereunder.

4.2 Customer is responsible for ensuring that Customer's technology transferred to Supplier pursuant to Section 4.1 in accordance with the Tech Transfer Plan does not infringe any Third Party's Intellectual Property Rights.

4.3 Supplier shall be responsible for obtaining and Maintaining all equipment required for the Fill/Finish and supply of Drug Product hereunder. Title to such equipment shall be in Supplier's name.

5. QUALITY AGREEMENT

5.1 The Parties shall negotiate in good faith and enter into both QA2 and QA3 within [***] of the Effective Date (or such extended period as mutually agreed by the Parties in writing). Upon execution QA2 and QA3 shall each be attached to Exhibit 2.

5.2 If there is any inconsistency between QA1, QA2 and QA3, a Product Schedule or an Exhibit, on the one hand, and the body of this Agreement, on the other hand, the [***] shall govern. Notwithstanding the foregoing, in the event of a conflict between any of the provisions of this Agreement and either QA1, QA2 or QA3 with respect, [***], the provisions of [***], shall govern, (b) [***], shall govern, and (c) [***], shall govern.

5.3 The Parties shall, at any Party's reasonable request, establish a joint project team, which shall discuss and propose updates and amendments to the Applicable Standards or Product Requirements for mutual written approval by the Parties (not to be unreasonably withheld, conditioned or delayed).

6. FORECASTS AND ORDERS – DRUG PRODUCT

Within [***] after Protalix's receipt of the forecast provided by Chiesi pursuant to any applicable License Agreement, Customer shall provide Supplier with a non-binding rolling Forecast for Customer's and its Affiliates' requirements of Drug Products during the following [***] ("Forecast"), which Forecast shall be based [***] submitted to Protalix under the applicable License Agreement. The Forecast will be allocated per quarter. The Forecast submitted in June each year ("June Forecast") shall, however, cover [***] under the License Agreements, and include an [***] for each quarter if the term of the Product Schedule continues for the following year. With respect to any given Drug Product, additional details regarding Forecasts for such Drug Product may be set forth expressly in the applicable Product Schedule.

7. FORECASTS AND ORDERS – DRUG SUBSTANCE

7.1 [***], the Parties shall consult with a view to develop a mutually-agreed upon strategy for maximizing Supplier's Fill/Finish commercial production yield of Drug Product(s) from the Drug Substance.

If, [***], Supplier's aggregate Fill/Finish commercial production yield of Drug Product(s) from the Drug Substance during such period is [***] of the Theoretical Yield, as calculated [***] from [***] (such excess consumption, the "Excess DS Consumption"), the Parties will promptly, and in good faith, meet to collectively evaluate the underlying cause of such Excess DS Consumption and discuss proposed corrections where appropriate.

In the event of Excess DS Consumption, [***]. For the avoidance of doubt, for purposes of calculating the Excess DS Consumption, any [***]. Further, it shall not constitute a breach of this Agreement by Supplier if Supplier's actual yield of Drug Product from Drug Substance hereunder is [***] of the Theoretical Yield.

7.2 On the Effective Date, or such later date that is at least [***], Customer shall deliver to Supplier a firm purchase order (a "DP Purchase Order") for the Drug Product for the first Commercial Quarter (as used throughout herein, as defined in the applicable License Agreement) covered by the initial Forecast and for at least [***], all of which shall be based on Chiesi's purchase orders and forecasts for Drug Product (submitted to Protalix under the applicable License Agreement) for [***]. Thereafter, [***], Protalix shall deliver to Chiesi a DP Purchase Order for the first Commercial Quarter covered by its Forecast and for at least [***], all of which shall be based on Chiesi's purchase orders and forecasts for Drug Product (submitted to Protalix under the applicable License Agreement) for [***]. DP 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 DP Purchase Order delivered by Protalix to Chiesi pursuant to this Section 7.2 shall be binding on Chiesi unless Chiesi notifies Protalix in writing of its rejection thereof within [***] of receipt of such DP Purchase Order; provided that

Chiesi may only reject DP Purchase Orders that are [***]. Each DP Purchase Order accepted by Supplier in accordance with this Agreement is non-cancellable by Customer, unless otherwise agreed in writing by Supplier in each instance. With respect to a given calendar year during the Term, Supplier agrees to have available Fill/Finish production capacity to supply Customer with quantities of Drug Product in aggregate for such calendar year at least [***] (provided, for purposes of clarity, Supplier will have no such obligation until the calendar year immediately following the calendar year in which [***]), but shall not be required to maintain Fill/Finish production capacity in excess thereof; provided, for clarity, that, [***], the available Fill/Finish production capacity of Supplier shall be [***]. Upon reasonable request of either Party, the Parties agree to discuss in good faith the potential for Fill/Finish of any such excess quantities of Drug Product.

7.3 DP Purchase Orders may be delivered electronically or by other means to such location as Supplier shall designate. Nothing in any such DP Purchase Order or written acceptance shall supersede the terms and conditions of this Agreement, the License Agreements, or the QA. All DP Purchase Orders, confirmations of receipt of DP Purchase Orders and other notices contemplated under this Section 7.3 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 21.8.

7.4 Supplier shall use its inventory of the Drug Substance in accordance with the order of allocations reasonably specified by Customer in writing (in conjunction with delivery of the applicable Drug Substance), and the Parties shall work together in good faith to review and resolve any reasonable concerns with respect to such use of Drug Substance.

8. DELIVERY OF DRUG PRODUCT

8.1 During the Term, Chiesi shall perform the Fill/Finish and deliver the resulting Drug Product for Customer [***]. Except as otherwise specified herein, [***]; provided that a failure by Supplier to detect a latent defect in such inspection and release conducted upon its receipt of Materials provided by its suppliers shall not be a breach of this Section 8.1.

8.2 Title to the Drug Product shall transfer to Chiesi upon [***] and, in any case, not later than [***] after [***] of the Drug Product, provided that at or prior to such time Protalix shall have invoiced Chiesi for such delivery of Drug Product pursuant to Section 4.6(a)(i) of the License Agreement.

8.3 Supplier will label and package all Drug Product as “Brite Stock” for bulk storage, including batch number(s) identification by batch number printing on each vial, in accordance with the QA; provided, however, that any Drug Product shall be retained by Supplier until each of Supplier and Customer has successfully completed its part of the release activities relating to such Drug Product pursuant to the applicable Product Requirements, the QA or the terms hereof.

8.4 In the event that the Materials or manufacturing capacity required to perform Fill/Finish and to supply Drug Product required hereunder are in material short supply (“Shortage”), Supplier shall notify Customer of such Shortage as soon as practicable after Supplier becomes aware of such Shortage or of circumstances that are reasonably likely to result in such a Shortage and the Parties shall promptly meet to discuss the Shortage (which discussion may be conducted through the Operating Committee). Supplier shall provide to Customer 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. Supplier shall [***] to minimize the duration of any Shortage. During any such Shortage, Supplier shall; [***].

8.5 Supplier shall promptly communicate any anticipated deviation from the amount of Drug Product(s) or delivery date previously specified in the corresponding accepted DP Purchase Order, in order to enable Customer to take necessary action to mitigate the effects thereof. Such notice shall include the reason for the anticipated deviation (i.e., the shortfall or delay) and provide an indication of the anticipated extent or duration of the same. In any such case, either Party may request that designated technical personnel from each Party undertake discussions regarding [***].

9. DELIVERY OF DRUG SUBSTANCE

9.1 During the Term, Customer shall supply and deliver the Drug Substance to Supplier [***], in a timely manner and in the quantities (a) that satisfy Supplier's requirements (as agreed to by the Parties in writing in advance) to Fill/Finish the quantities of Drug Product ordered by Customer under DP Purchase Orders submitted to, and accepted by Supplier, from time to time in accordance with the terms of this Agreement and (b) of additional backup and replacement quantities of Drug Substance as specified in the applicable Product Schedule or in Sections 9.2, 9.3 (and 9.5, if applicable), 9.4 (and 9.5, if applicable), 13.9 and 13.10. For clarity, Supplier would remain responsible for [***], if applicable. All Drug Substance must be delivered to Supplier [***] in advance of the manufacturing commencement date for the applicable Drug Product, and the Parties agree to coordinate in this regard.

9.2 Upon receipt of any Drug Substance at Supplier's facility in accordance herewith, Supplier shall perform a visual inspection of the Drug Substance as contemplated by the Product Schedule and/or the QA. If such inspection reveals that any delivery of the Drug Substance is patently damaged, short in quantity or if there are apparent discrepancies between the delivered Drug Substance and the Customer's Manufacturing Certificate of Analysis, Supplier shall promptly [***] notify Customer of the same and Customer shall [***] promptly provide to Supplier replacement Drug Substance therefor (provided, for clarity, that Supplier may utilize any backup inventory of Drug Substance as necessary to meet production timelines in accordance with this Agreement, which utilization shall be subject to the pre-approval of Customer (not to be unreasonably withheld, conditioned, or delayed), and the Parties shall work together in good faith to review and resolve any reasonable concerns with respect to such use of Drug Substance).

9.3 In the case of any (a) Non-Conformance (including any latent defects) of Drug Substance discovered following its delivery to Supplier by Customer hereunder after the notice period set forth in Section 9.2 or (b) Drug Substance that is consumed, damaged, lost or rendered unusable in the course of Fill/Finish production of Drug Product by Supplier hereunder ("Processed Drug Substance"), then in each case ((a) and/or (b)), (y) Customer shall [***] promptly provide to Supplier replacement Drug Substance therefor (provided, for clarity, that Supplier may utilize any backup inventory of Drug Substance as necessary to meet production timelines in accordance with this Agreement, which utilization shall be subject to the pre-approval of Customer (not to be unreasonably withheld, conditioned, or delayed), and the Parties shall work together in good faith to review and resolve any reasonable concerns with respect to such use of Drug Substance), and (z) [***].

9.4 In the case of any (a) Drug Substance or (b) Drug Substance contained in Bulk Drug Product, that is damaged, lost or stolen while in the possession of Supplier hereunder (e.g., during storage) (but excluding Processed Drug Substance) ("Lost Drug Substance"), (y) [***]; and (z) Customer shall [***] promptly provide to Supplier replacement Drug Substance therefor (provided, for clarity, that Supplier may utilize any backup inventory of Drug Substance as necessary to meet production timelines in accordance with this Agreement, which utilization shall be subject to the pre-approval of Customer (not to be unreasonably withheld, conditioned, or delayed), and the Parties

shall work together in good faith to review and resolve any reasonable concerns with respect to such use of Drug Substance).

9.5 In the event that replacement of Drug Substance becomes necessary under this Agreement, or Non-Conformance, damage, loss of Drug Substance otherwise occurs (or Drug Substance is otherwise rendered unusable), the Parties shall conduct a root cause investigation with respect to the same, as contemplated by the QA, including using applicable lab testing and analysis, and, in the case of any differences in the results of the Parties' initial root cause analysis, work together in good faith to resolve the same as promptly as practicable.

9.6 Supplier's use of the Drug Substance received from Customer shall be limited to the Fill/Finish of Drug Product for Customer hereunder.

10. DEFECTS, SHORTFALL, DAMAGE TO DRUG PRODUCT

10.1 Without limiting the provisions of Section 8.4, in case of any material damage, defect [***] or shortage, as compared to the requirements under this Agreement (a "Non-Conformance"), in or of the Drug Product supplied to Customer hereunder, Customer will promptly give Supplier a written notice thereof in accordance with the QA. Without limiting Customer's other audit rights hereunder, Customer shall also have a reasonable opportunity to [***] from time to time as contemplated by the QA.

10.2 In the event of any Non-Conformance with respect to the Drug Product Fill/Finished by Supplier hereunder, Supplier shall replace such non-conforming Drug Product with conforming Drug Product, [***].

10.3 If the Parties do not agree as to the cause of an alleged Non-Conformance of Drug Product for which Customer has provided notice in accordance with Section 10.1, the Parties shall promptly discuss and in good faith attempt to resolve such dispute; provided, however, Supplier shall [***] to [***] replace such alleged non-conforming Drug Product to try and avoid any possible out-of-stock situation. The Parties shall use [***] to resolve the dispute in the case of Non-Conformance or OOS, within [***] unless otherwise agreed in writing by the Parties. If the dispute is not resolved by the Parties in such period or such other period as the Parties may agree to apply to an independent expert mutually selected by the Parties for determination of the cause and/or existence of such alleged Non-Conformance. The expert shall be mutually agreed upon in writing by the Parties and engaged by Customer. The results of the expert's determination shall be based on [***], and shall be final and binding on the Parties (absent manifest error or fraud), [***].

11. INVOICES

11.1 Each delivery of Drug Product hereunder shall be accompanied by an invoice. Supplier shall invoice for the Drug Product at the price that is determined in accordance with the applicable Product Schedule. Customer shall issue payment against such undisputed invoices within [***] of the invoice date. Supplier shall include the following information, where applicable, on all invoices: the type, description, and quantity of the Drug Product delivered; the date of shipment; the prices; any applicable taxes, transportation charges or other charges provided for hereunder; and the applicable purchase order number.

11.2 All invoices will be raised in Euros, and Customer agrees to pay all sums due in this currency.

11.3 Customer may withhold payment of that portion of any charges that Customer reasonably disputes in good faith subject to the following:

(a) if Customer disputes any charges, Customer shall so notify Supplier and provide a description of the particular invoice(s) in dispute and an explanation of the reason why Customer disputes such invoice(s);

(b) neither the failure to dispute any charges prior to payment nor the failure to withhold any amount shall constitute, operate or be construed as a waiver of any right Customer may otherwise have to dispute any such invoice(s) or recover any amount previously paid; and

(c) Customer shall pay the remaining, undisputed charges in accordance with the terms of this Article 11.

11.4 If an undisputed invoice is not paid within this timeframe, penalty interest shall be charged to the Customer. Penalty interest shall be equal to the lesser of (i) the maximum rate permitted by Applicable Law, or (ii) [***] per month, computed monthly from the payment due date as indicated in the invoice and until complete payment is received.

12. TAX MATTERS

12.1 Taxes. [***].

12.2 VAT. It is understood and agreed between the Parties that any payments made to Supplier under this Agreement are exclusive of any value added or similar tax imposed upon such payments, [***].

12.3 Withholding Tax. Payments made by Customer to Supplier pursuant to this Agreement shall be made [***]. If Supplier disputes either the requirement to deduct such tax withholding or deduction from such payment, or the amount of such withholding or deduction (including where Supplier, acting in good faith, considers that less onerous taxation arrangements are available to the Parties), the Parties shall [***], independent accounting firm of reputable stature with relevant taxation expertise in the relevant jurisdiction to provide its professional opinion as to existence of, and the relevant amount in respect of, such tax liability. [***], and such independent accounting firm's determination as to the existence of, and amount of, such tax liability shall be binding on the Parties, in respect of the application of this Section 12.3 to such payment (unless an applicable Governmental Authority later determines the requirement and the amount of such withholding or deduction, in which case, such determination by such applicable Governmental Authority shall be binding on the Parties in respect of the application of this Section 12.3 to such payment). For the avoidance of doubt, to the extent Supplier disputes either the requirement to deduct such tax withholding or deduction from such payment, or the amount of such withholding or deduction, and unless either an applicable Governmental Authority or a [***] independent accounting firm has otherwise determined the existence of, and amount of, such taxation liability in respect of such payment in accordance with the terms of this Section 12.3, [***]. In each case, Customer shall pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Supplier an official tax certificate or other evidence of such payment of such deduction or withholding tax if Supplier might be affected under this Section 12.3 [***]. Notwithstanding the foregoing, if as at the date on which a payment from Customer to Supplier under this Agreement is due and payable, Supplier has not yet made available to Customer the certifications needed to reduce the amount of the withholding tax under Applicable Law, then Customer shall not be responsible [***] for any withholding tax higher than [***].

12.4 Cooperation. Each Party shall provide the other with reasonable assistance to enable a reduction in, elimination of, or the recovery, as permitted by Applicable Law, of withholding taxes, VAT, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or VAT. Each Party shall provide reasonable notice to the other Party

of the notifying Party's intent to withhold any amount in respect of taxes, and the other Party shall provide to the notifying Party any tax forms that may be reasonably requested by and necessary for the notifying Party not to withhold tax or to withhold tax at a reduced rate under Applicable Law (including an applicable income tax treaty). Each Party further agrees to provide reasonable cooperation to the other Party, at the other Party's expense, in connection with any official or unofficial tax audit or contest relating to payments made by a Party to the other Party under this Agreement.

13. QUALITY, AUDITS, AND REGULATORY MATTERS

13.1 In conducting the Fill/Finish hereunder, Supplier shall apply its quality control procedures and in-plant quality control checks on such Fill/Finish in the same manner as Supplier applies such procedures and checks to products of similar nature manufactured for sale by Supplier. In addition, Supplier and Customer shall each comply with all Applicable Laws, the QA, the Product Schedule, Applicable Standards and the Fill/Finish Licenses in its performance hereunder. Supplier shall Fill/Finish Drug Product under this Agreement in compliance with Applicable Standards and the Product Requirements.

13.2 Supplier shall ensure that it, [***], obtains and maintains throughout the Term the Fill/Finish Licenses and other Regulatory Authority certificates, permits, licenses or approvals that it (or the relevant Affiliate) respectively requires for the performance of Fill/Finish hereunder.

13.3 The Parties agree to cooperate in attempting to resolve all product quality complaints as set out in the QA and will test and release Drug Product in accordance with the test methods as set forth in the QA to ensure that Drug Product conforms to the requirements set forth in the last sentence of Section 13.1 above. For clarity, at the time of the Agreement, Supplier will be responsible for only the following testing with respect to release of Drug Product hereunder: [***]. The Parties will in good faith use [***] to transfer to Supplier all other testing of Drug Product for release [***]. Following completion of such transfer, Supplier will be responsible for all testing for release and stability as contemplated by the QA for Drug Product Fill/Finished by Supplier for Customer hereunder. Upon Supplier's request, Customer will support the testing at a back-up testing lab.

13.4 Supplier shall notify Customer in advance of, and obtain its prior written approval before, implementing [***]. The Parties shall, at Supplier's or Customer's reasonable request, establish a joint project team, which shall discuss and agree on the details of such changes and program of their implementation (not to be unreasonably withheld, conditioned or delayed). All approved changes will be implemented in accordance with the provisions of the QA, as applicable, and except as otherwise set forth this Agreement, as between Chiesi and Protalix under this Agreement, all associated costs and expenses of [***].

13.5 Supplier shall prepare and maintain accurate records and books relating to the Fill/Finish performed hereunder in accordance with Applicable Law and the QA.

13.6 Customer shall have the right to conduct, at its sole expense at a frequency defined in the QA, during normal business hours (at times mutually agreed by the Parties) and subject to a [***] prior written notice to Supplier, a general quality assurance audit and inspection of Supplier's records and production or testing facilities relating to the Fill/Finish of the Drug Product for Customer hereunder, including storage of Drug Substance and the Drug Product in the course thereof. Representatives of Customer shall have access during audits to those areas of the facility where the Fill/Finish with respect to the Drug Product, including storage of Drug Substance and Drug Product in the course thereof, are performed, all documents, records, reports, data, procedures, regulatory submissions, and other information required to be maintained by the relevant

regulatory authorities by Applicable Laws corresponding to Supplier's Fill/Finish of Drug Product hereunder. All audited documents, data, reports, procedures, regulatory submissions, information and records, as well as anything visually observed or learned during such audit or while present in the facility, will be treated as Confidential Information of Supplier, and Customer will not be permitted to remove or copy such Confidential Information without Supplier's prior written consent.

13.7 Supplier shall permit Customer to conduct "for cause audits" as [***] to address significant product or safety concerns as discovered through the audits conducted by Customer under Section 13.6. Any deficiencies identified in an audit or inspection by Customer pursuant to this Article 13 shall be handled and remediated in accordance with the QA.

13.8 Supplier also agrees to allow the FDA and other relevant Regulatory Authorities to conduct any inspection/audit that any such Regulatory Authority requires, and Supplier agrees to cooperate with and provide such documentation or assistance as may be requested by the FDA or any other Regulatory Authority, as the case may be, in connection with such inspection/audit.

13.9 Supplier shall, subject to Section 13.12, [***], correct each deficiency identified by the applicable Regulatory Authority in an audit or inspection described in Section 13.8 (excluding in each case Regulatory Inspection Deficiencies, which, for clarity, shall be treated in accordance with Section 13.10, [***].

13.10 In the event that any Regulatory Authority shall determine (and notifies Supplier in writing), as a result of such inspection (conducted under Section 13.8 above), that Supplier is not [***] with Applicable Laws (including cGMP) with respect to Supplier's performance of the Fill/Finish activities for the Drug Product hereunder ("Regulatory Inspection Deficiency"), [***], and subject to Section 13.12, Supplier shall cure such Regulatory Inspection Deficiency [***], provided that [***].

13.11 With respect to any Regulatory Inspection Deficiency that: [***] (a "Critical Regulatory Inspection Deficiency"), [***], Supplier shall [***]. In the event that a Critical Regulatory Inspection Deficiency occurs [***], either Party may [***] upon written notice to the other Party, provided that: [***].

13.12 Supplier is not responsible for any inspection deficiencies contemplated by Section 13.7, Section 13.9, Section 13.10 (including any Regulatory Inspection Deficiency) or Section 13.11 (including any Critical Regulatory Inspection Deficiency), in each case, [***] such inspection deficiency, Regulatory Inspection Deficiency or Critical Regulatory Inspection Deficiency is caused by compliance with Customer's written instructions with respect to the Fill/Finish process transferred to Supplier pursuant to the Tech Transfer or Customer's breach or failure in its performance hereunder, including delays in performing reviews or providing approvals or information, technology, instructions, documents, or other items (including Drug Substance) required to be supplied by or on behalf of Customer hereunder ("Dependency Event – Inspection Deficiency"), [***].

13.13 Supplier shall keep Customer apprised of the status of all interactions and communications with the FDA and other Regulatory Authorities, including, no later than [***], notifying Customer in writing of, and providing Customer with copies of, any correspondence, communications and other documentation received from the FDA or other Regulatory Authority relating to the Drug Substance, Drug Product, or conduct of the Fill/Finish hereunder (including without limitation any general cGMP inspection applicable to the facility) as contemplated by the QA. Supplier shall [***] to consult with Customer in advance of any meeting or discussion, either in person or by telephone or videoconference, with the FDA or Regulatory Authority in connection with the Drug Substance, Drug Product or conduct of Fill/Finish hereunder. As

requested by Supplier, Customer shall promptly review and comment on any proposed response of Supplier to any Regulatory Authority.

13.14 During [***], Supplier will permit [***] to observe and consult with Supplier during the conduct of [***] in respect of the Drug Product. With respect to the foregoing, Supplier will provide [***] with reasonable access to the portion of Supplier's facility used to conduct such [***] in order to observe such [***]. Supplier will provide Customer with sufficient advance notice of each such [***] accordingly, provided that in no event will this Section 13.14 be deemed to require Supplier to delay or reschedule any such [***].

13.15 During any visits to or inspections of Supplier's facility, [***] will abide by all Supplier policies and procedures in force at Supplier's facility.

14. RECALLS OR OTHER CORRECTIVE ACTION

In the event of any required or voluntary recall, withdrawal, field alert or similar action for the Drug Product (a "Recall"), such Recall shall be handled in accordance with the License Agreements and QA. For clarity, as between the Parties under this Agreement, the Parties' respective responsibility, if any, for the costs and expenses of any Recall [***], and (b) this Article 14 does not modify (and shall not be interpreted as modifying) any provisions of the License Agreement relating to any recall, withdrawal, field alert or similar actions, including Recalls.

15. CONFIDENTIALITY

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

15.2 Permitted Disclosures. Notwithstanding the foregoing, each Party may disclose the other Party's Confidential Information (a) to such Party's employees, consultants (including, for greater certainty, financial advisors), Affiliates, agents, contractors, or permitted sublicensees who are bound by obligations relating to confidentiality at least as restrictive of those contained herein and who have a need to know such information in connection with such Party's performance of its obligations or practice or enforcement of its rights under this Agreement, (b) to Regulatory Authorities in connection with any regulatory approvals required for the Drug Product pursuant to the License Agreements or in compliance with Applicable Laws, rules and regulations, including any requirements under or pursuant to the Food and Drug Administration Amendments Act of 2007, or (c) pursuant to Sections 15.3 and 15.4.

15.3 Terms of Agreement. The Parties agree that the material terms of this Agreement will be considered Confidential Information of both Parties. Subject to Section 15.4 below, no Party shall, without the prior written consent of the other Party, disclose in any manner to any Third Party the material terms and conditions of this Agreement, except for terms or subject matter which has been the subject of prior public disclosure or has been mutually approved for such disclosure and except as set forth below. Supplier acknowledges that Customer or its Affiliates may be legally required to file this Agreement as an exhibit to filings with the U.S. Securities and Exchange Commission. In addition: (a) either Party may disclose such terms as are required to be disclosed in its publicly-filed financial statements or other public statements, pursuant to Applicable Laws, regulations and stock exchange rules (e.g., the rules of the U.S. Securities and Exchange Commission, the NYSE American, the NYSE, NASDAQ, or any other stock exchange on which securities issued by either Party may be listed); provided that such

Party shall provide the other Party with a copy of the proposed text of such statements or disclosure (including any exhibits containing this Agreement) sufficiently in advance of the scheduled release or publication thereof to afford such other Party a reasonable opportunity to review and comment upon the proposed text (including redacted versions of this Agreement) and the disclosing Party shall reasonably consider such comments in good faith and (b) either Party shall have the further right to disclose the terms of this Agreement under a confidentiality obligation no less protective than those set forth in this Agreement, to any potential sublicensee, acquirer, merger partner, investor, business partner or potential providers of financing and their advisors.

15.4 Mandatory Disclosure.

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

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

16. REPRESENTATIONS, WARRANTIES AND COVENANTS

16.1 Each of Customer and Supplier hereby represents and warrants to the other Party as of the Effective Date (or covenants as set forth in Sections 16.1(g), (h), (i), and (j) below) as follows:

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

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

(c) Assuming the due authorization, execution and delivery by the other Party, this Agreement constitutes a legally valid and binding obligation of such Party, enforceable against it in accordance with its terms (except in all cases as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting the enforcement of creditors' rights generally and except that the availability of the equitable

remedy of specific performance or injunctive relief is subject to the discretion of the court or other tribunal before which any proceeding may be brought).

(d) There is no contractual restriction or obligation binding on such Party which would be materially contravened by execution and delivery of this Agreement or by the performance of its terms. There are no governmental filings or consents necessary for the execution of this Agreement.

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

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

(g) During the Term, each Party shall promptly notify the other Party in writing upon learning of any actual or threatened investigation, inquiry, action or proceeding by or before the FDA or any other Regulatory Authority with respect to the conduct of Fill/Finish activities hereunder.

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

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

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

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

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

(j) Unless to the extent this provision would be a violation of any Applicable Laws, Customer shall promptly notify Supplier at the following Supplier e-mail address: groupcompliance@chiesi.com, and Supplier shall promptly

notify Customer at the following Customer e-mail address: dror.bashan@protalix.com, if such Party becomes aware of:

(i) any request, promise, offer, or donation of money, commission, compensation or rewards in kind (including gifts, entertainments, or any other similar benefit, even low value or non-material benefits) made to public officers, private parties or the other Party's directors, legal representatives or employees (or whoever acts on behalf of such other Party), in relation to the activities prohibited under Section 16.1(i);

(ii) any gift, entertainment or any other similar benefit, even non-material benefits, carried out by either Party in breach of the provisions of Section 16.1(i); or

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

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

16.2 Supplier hereby:

(a) represents, warrants and covenants to Customer that: (i) Supplier shall conduct, and shall use reasonable efforts to cause its Affiliates assigned responsibilities hereunder to conduct, all its activities contemplated under this Agreement in compliance with all of the provisions and requirements of the QA and in material compliance with all Applicable Laws, and (ii) the Drug Product delivered to Customer hereunder shall have been [***]; and

(b) covenants to Customer that it will inform Customer promptly in writing of any event, circumstance or condition, which in the reasonable judgment of

Supplier, may adversely affect (i) Supplier's ability to conduct the Fill/Finish hereunder or (ii) the suitability of the Drug Product for incorporation into Licensed Product for commercial sale in the Field worldwide.

16.3 Customer hereby represents, warrants and covenants to Supplier as follows:

(a) that (i) Customer shall conduct, and shall use reasonable efforts to cause its Affiliates assigned responsibilities hereunder to conduct, all its activities contemplated under this Agreement in compliance with all of the provisions and requirements of the QA and in material compliance with all Applicable Laws, and (ii) the Drug Substance delivered to Supplier hereunder, shall comply with all registered specifications for the Drug Substance, Product Requirements, and Applicable Standards and the QA;

(b) it has, and will maintain throughout the Term of this Agreement, appropriate Regulatory Approvals for the Drug Substance and it has notified Supplier of any special requirements in respect of recordkeeping that may be necessary to comply with Customer's adverse event, Drug Substance, Drug Product, defect or Recall procedures and that it shall notify Supplier of any hazards to the health or safety of any personnel of Supplier or the possibility of cross contamination of any other products being supplied or stored by Supplier and Customer shall keep Supplier so advised throughout the continuance of this Agreement, whether such hazards or possibilities are inherent in the Drug Substance, Drug Product or otherwise;

(c) (i) it has the right to grant the license to Customer's Background Intellectual Property and Customer Intellectual Property granted to Supplier hereunder, (ii) to its knowledge, Supplier's practice of Customer's Background Intellectual Property and Customer Intellectual Property as contemplated by this Agreement will not infringe any Intellectual Property Rights of any Third Party, and (iii) it has not, as of the Effective Date, granted, conveyed or otherwise transferred, and will not, during the Term, grant, convey or otherwise transfer, in each case, whether directly or indirectly, any rights or license to any Third Party in a manner that conflicts with such license granted to Supplier by Customer hereunder; and

(d) the Tech Transfer, upon completion thereof in accordance with the terms of this Agreement, will be a complete and accurate transfer to Supplier of all know-how with respect to the Fill/Finish process for the Drug Product, except as would not constitute a material and adverse effect on the ability of Supplier to perform its Fill/Finish obligations hereunder.

16.4 EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY, AND EACH PARTY DISCLAIMS ALL, REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, WITH RESPECT TO THE DRUG SUBSTANCE AND THE DRUG PRODUCT, OR ANY OTHER MATTER RELATED TO THIS AGREEMENT, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

16.5 [***].

17. INDEMNIFICATION; LIMITATION OF LIABILITY

17.1 Indemnification by Supplier. Subject to Sections 17.3 and 17.4, Supplier shall indemnify, defend and hold Customer, its Affiliates, and their respective Representatives (collectively, the "Customer Indemnitees") harmless from and against any and all claims, suits, proceedings or causes of action ("Claims") brought by a Third

Party against such Customer Indemnitee, including any damages or other amounts payable to such Third Party and reasonable attorneys' fees and costs of litigation (collectively, "Damages"), in each case to the extent resulting from or arising out of: (a) Supplier's breach of this Agreement or its covenants or breach of any of its representations or warranties; (b) Supplier's failure to comply with Applicable Law; or (c) the gross negligence, fraud, or willful misconduct of Supplier or its Affiliates, or their respective Representatives in the performance of this Agreement; in each case, to the extent not resulting from or related to Customer's breach of its obligations under this Agreement or its, its Affiliates', or their respective Representatives' gross negligence or willful misconduct or otherwise subject to Customer's indemnification obligations pursuant to Section 17.2 below.

17.2 Indemnification by Customer. Subject to Sections 17.3 and 17.4, Customer shall indemnify, defend and hold Supplier, its Affiliates, and their respective Representatives (collectively, the "Supplier Indemnitees") harmless from and against any and all Claims brought by a Third Party against such Supplier Indemnitee, including any Damages, in each case to the extent resulting from or arising out of: (a) Customer's breach of this Agreement or its covenants or breach of any of its representations or warranties herein; (b) any claim of infringement or misappropriation of any Intellectual Property Right of any Third Party to the extent such claim arises with respect to the Drug Substance, Drug Product, Customer's Background Intellectual Property or Customer Intellectual Property; (c) Customer's failure to comply with Applicable Law; or (d) the gross negligence, fraud, or willful misconduct of Customer, its Affiliates, licensees or sublicensees, or their respective Representatives; in each case, to the extent not resulting from or related to Supplier's breach of its obligations under this Agreement or its, its Affiliates', or their respective Representatives' gross negligence or willful misconduct or otherwise subject to Supplier's indemnification obligations pursuant to Section 17.1 above.

17.3 Indemnification of Product Liability Claims. This Section 17.3 shall govern the allocation of liability, as between the Parties under this Agreement (without limiting the applicable License Agreement(s)), with respect to any Third Party product liability Claim for property injury, bodily injury or deaths resulting from the Drug Product (a "Third Party Product Claim"). Subject to Section 17.4, Supplier shall indemnify and hold harmless the Customer Indemnitees from and against any and all Damages which a Customer Indemnitee may incur or suffer arising out of any Third Party Product Claim solely to the extent [***]; provided, that Customer shall not be entitled to indemnification pursuant to this Section 17.3, (y) to the extent such Claim or Damages is/are subject to Customer's indemnifications obligations under Section 17.2, and (z) for any amount to the extent that Protalix has been indemnified for such amount under Section 13.3(b) of the applicable License Agreement(s); [***]. The indemnification provided pursuant to this Section 17.3 shall be the sole and exclusive remedy of Customer for any and all Damages arising out of a Third Party Product Claim.

17.4 Defense Procedures; Procedures for Third Party Claims.

(a) For purposes of this Agreement, "Third Party Claim" means a Claim asserted by a Third Party (in no event to include any Affiliate of either Party) against a Party or any of its Affiliates, or any of their respective directors, officers, employees, consultants, contractors, sublicensees and agents. In the event a Third Party Claim is asserted with respect to any matter for which a Party or any of its Affiliates, or any of their respective directors, officers, employees, consultants, contractors, sublicensees and agents (the "Indemnified Party") is entitled to indemnification hereunder, then the Indemnified Party shall promptly notify in writing the Party obligated to indemnify the Indemnified Party hereunder (the "Indemnifying Party") thereof; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying

Party shall relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

(b) 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 17.1, 17.2, and 17.3, as applicable, solely for such Third Party Claim and related Damages.

(c) Neither Party will enter into any settlement of any suit involving a Third Party Claim that materially affects the other Party's rights or obligations without the other Party's prior written consent (which consent shall not be unreasonably withheld, delayed or conditioned). The Indemnifying Party shall not, without the written consent of the Indemnified Party (which consent shall not be unreasonably withheld, delayed or conditioned), effect any settlement of any pending or threatened litigation in which the Indemnified Party has sought indemnification hereunder by the Indemnifying Party, unless such settlement involves solely monetary damages and includes an unconditional release of the Indemnified Party from all liability on Claims that are the subject matter of such litigation.

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

17.6 Disclaimer of Liability for Consequential Damages. IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS RESPECTIVE AFFILIATES BE LIABLE UNDER THIS AGREEMENT FOR SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUE SUFFERED BY SUPPLIER, CUSTOMER OR ANY OF THEIR RESPECTIVE AFFILIATES. THE FOREGOING SENTENCE SHALL NOT LIMIT THE EXPRESS OBLIGATIONS OF EITHER PARTY TO INDEMNIFY THE OTHER PARTY FROM AND AGAINST THIRD PARTY CLAIMS UNDER SECTIONS 17.1, 17.2, AND 17.3 OF THIS AGREEMENT OR LIABILITIES RESULTING FROM A PARTY'S BREACH OF THE CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 15, BREACH OF ARTICLE 20, WILLFUL MISCONDUCT, OR FRAUD.

17.7 Limitations of Liability. EXCEPT WITH RESPECT TO A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 17.1, SECTION 17.2, OR SECTION 17.3, AS APPLICABLE, BREACH OF ARTICLE 15 OR ARTICLE 20, OR GROSS NEGLIGENCE [***], WILLFUL MISCONDUCT OR FRAUD, IN NO EVENT SHALL:

(a) SUPPLIER'S TOTAL LIABILITY UNDER THIS AGREEMENT, INCLUDING FOR ALL CLAIMS OF ANY KIND, WHETHER IN CONTRACT, TORT OR STRICT LIABILITY, ARISING OUT OF THE PERFORMANCE OR BREACH OF THIS AGREEMENT, FOR ANY DRUG SUBSTANCE, DRUG PRODUCT, OR REPLACEMENT OF DRUG SUBSTANCE OR DRUG PRODUCT, OR FOR COST OF RECALLS HEREUNDER, EXCEED, [***],

(i) [***];

(ii) [***];

(iii) [***];

(iv) [***];

(v) [***]; AND

(vi) [***].

(b) CUSTOMER'S TOTAL LIABILITY UNDER THIS AGREEMENT, INCLUDING FOR ALL CLAIMS OF ANY KIND, WHETHER IN CONTRACT, TORT OR STRICT LIABILITY, ARISING OUT OF THE PERFORMANCE OR BREACH OF THIS AGREEMENT, EXCEED [***].

(c) SUPPLIER BE REQUIRED TO REIMBURSE CUSTOMER FOR [***];

PROVIDED THAT [***]; THE FOREGOING LIMITATIONS SHALL APPLY NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY.

17.8 Notwithstanding anything to the contrary herein, Supplier shall not be liable for any Non-Conformance, or delay, with respect to Drug Product arising hereunder, [***] that such Non-Conformance or delay is caused by the Drug Substance, a Force Majeure Event [***], defective Materials supplied by Customer (in the condition in which the same were supplied by Customer hereunder), compliance with Customer's written instructions, or Customer's failure to: (a) comply with its responsibilities or (b) take actions or provide instructions required to be taken or provided (as applicable) hereunder ("Dependency Event"), [***].

17.9 [***]

17.10 EXCEPT AS EXPRESSLY SET FORTH IN [***], SUPPLIER SHALL HAVE NO LIABILITY TO CUSTOMER WITH RESPECT TO DRUG SUBSTANCE HEREUNDER, AND IN ALL SUCH CASES, CUSTOMER IS RESPONSIBLE FOR ALL DAMAGE TO OR LOSSES (INCLUDING RENDERING UNUSABLE OR CONSUMPTION) OF DRUG SUBSTANCE UNDER OR IN CONNECTION WITH THIS AGREEMENT.

18. TERM AND TERMINATION

18.1 This Agreement shall continue in force from the Effective Date until December 31, 2025 (such period, the "Term"), unless terminated earlier in accordance with this Article 18. Thereafter, Customer and Supplier may extend the initial Term one time (1x) for an additional period of seven (7) years, upon mutual written agreement prior to expiration of the initial Term.

18.2 Unless otherwise specified in the applicable Product Schedule, each Product Schedule shall continue in force during the Term, unless terminated earlier in accordance with this Article 18.

18.3 This Agreement may be terminated immediately (in whole or in part) by either Party upon notice to the other Party:

(a) in the event of a material breach of this Agreement by the other Party and such material breach is not cured (i) within thirty (30) days after written notice thereof is delivered to the breaching Party, or (ii) in the case of a breach that cannot be cured within thirty (30) days, within a reasonable period not exceeding ninety (90) days after written notice thereof is delivered to the breaching Party, so long as the breaching Party is making a good faith effort to cure such default;

(b) if the other Party shall file in any court or agency, pursuant to any statute or regulation of any country, a petition in bankruptcy or insolvency or for reorganization or for an the appointment of a receiver or trustee of such other Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it, filed in any insolvency proceeding, that is not dismissed within sixty (60) days, or if the other Party shall propose or be a party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of its creditors; or

(c) in the event that both of the License Agreements expire or are terminated.

18.4 This Agreement may be terminated by either Party in accordance with [***].

18.5 Without prejudice to any other rights or remedies which either Party may have under this Agreement, upon the termination (or the applicable portion thereof) or expiration of this Agreement:

(a) Supplier shall: (i) return any remaining inventory of Drug Substance and Drug Product to Customer [***]; and (ii) promptly make available to Customer copies of all batch records and documentation relating to the Fill/Finish activities in respect of the Drug Product and shall store the originals or electronic copies of such documents and records according to cGMPs in accordance with Supplier's internal quality procedures and Applicable Laws, provided that Supplier shall not be required to store such records/documents beyond the duration required thereunder.

(b) Supplier will invoice Customer in respect of (i) Fill/Finish performed in accordance with the terms and conditions of this Agreement up to and including the effective date of such termination or expiration in full, for all completed Fill/Finish, and, for partially completed Fill/Finish, a sum calculated on a pro-rata basis (determined in good faith by Supplier), (ii) any out-of-pocket or other costs incurred by Supplier on behalf of Customer hereunder pursuant to the applicable Forecast; provided that Supplier shall use its reasonable efforts to mitigate such costs following the termination of this Agreement, and (iii) the TT Reimbursement Fee, in accordance with Exhibit 1 (as applicable). All such amounts are due and payable by Customer upon invoice delivery.

(c) Each Party shall: (i) immediately cease all use of any property of the other Party, including any Intellectual Property Rights of the other Party, under this Agreement; and (ii) within thirty (30) days of such termination, at its own expense, return to the other Party or destroy any Confidential Information of the other Party in its possession, custody or control, provided, however, that a

Party may retain one (1) copy of the other Party's Confidential Information in the confidential files of its legal department in order to ensure compliance with its obligations set forth in this Agreement and that Supplier may retain Confidential Information of Customer to the extent necessary for Supplier's performance under the License Agreements (and, for clarity, subject to the confidentiality, non-use and non-disclosure obligations therein).

19. **GOVERNING LAW AND JURISDICTION**

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

19.2 Jurisdiction and Dispute Resolution Process. With the exception of those matters referred for resolution by an independent expert under Section 10.3, or as otherwise specified elsewhere in this Agreement, any dispute, controversy or claim arising out of or relating to this Agreement, or the interpretation or breach thereof, including disputes regarding the existence, validity or termination of this Agreement or the scope of the agreement to arbitrate herein (each, a "Dispute"), shall be determined in accordance with the provisions of this Section 19.2:

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

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

(c) In any arbitration commenced pursuant to this Section 19.2:

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

(ii) The seat of arbitration shall be London, England. The language of the arbitration shall be English. The Parties agree that the award rendered by the arbitral tribunal shall be final and binding and enforceable against the Parties and their respective assets in any court of competent jurisdiction. Unless determined otherwise by the arbitral tribunal, each Party shall pay its own costs and expenses in connection with the arbitration, [***]. [***].

(iii) Any arbitration hereunder shall be confidential, and neither the Parties nor their agents shall disclose to any Third Party the existence or status of the arbitration, any information made known or documents

produced in the arbitration not otherwise available to them or in the public domain, or any awards arising from the arbitration, except and to the extent that disclosure is required by Applicable Law or is required to protect or pursue a legal right.

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

(v) In any action pursuant to Section 19.2 and in any action with respect to any arbitration award obtained pursuant to this Agreement or to the enforcement of such an award, the Parties agree to accept service of process in the manner provided for notices in this Agreement, and to waive any other requirements for service of process in any jurisdiction to the fullest extent permitted by law.

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

20. INTELLECTUAL PROPERTY

20.1 Background Intellectual Property. Except as the Parties may otherwise expressly agree in writing, each Party shall continue to own its existing Intellectual Property Rights, as well as the foregoing developed or acquired by such Party outside of this Agreement (collectively, "Background Intellectual Property"), without conferring any interests therein on the other Party. During the Term, Customer shall not, and shall cause its Representatives not to, assert any Intellectual Property Rights comprising Customer's Background Intellectual Property against Supplier, its Representatives or permitted sublicensees for performing Supplier's obligations and exercising Supplier's rights under this Agreement.

20.2 Customer Intellectual Property. Except for Supplier Intellectual Property, Customer shall own and retain all right, title and interest, including, without limitation, all Intellectual Property Rights, in and to all inventions, discoveries, improvements, know-how, information, and data that are made, conceived, reduced to practice, created, written, designed or developed by or on behalf of Customer and/or Supplier in the performance of Fill/Finish (collectively, "Customer Intellectual Property"); Supplier agrees to assign, and hereby assigns, to Customer all right, title, and interest in and to the Customer Intellectual Property. Customer hereby grants to Supplier a non-exclusive, non-transferable (other than in accordance with Section 21.6), royalty-free license, with the right to grant and authorize sublicenses (through multiple tiers), during the Term, under any and all Customer Intellectual Property that Customer has provided to Supplier, or is otherwise necessary or reasonably useful, for the purpose of performing Supplier's obligations and exercising Supplier's rights under this Agreement.

20.3 Supplier Intellectual Property. Supplier shall own and retain all right, title and interest, including, without limitation, all Intellectual Property Rights, in and to all inventions, discoveries, improvements, know-how, information, and data that are made, conceived, reduced to practice, created, written, designed or developed by or on behalf of Supplier in the performance of Fill/Finish to the extent (a) generally applicable to Supplier's

business and not specific to the Drug Product or Drug Substance and b) the practice of which does not require any use of Customer's Confidential Information (collectively, "Supplier Intellectual Property").

20.4 Except as otherwise expressly provided herein, nothing contained in this Agreement shall be construed or interpreted, either expressly or by implication, estoppel or otherwise, as (a) a grant, transfer or other conveyance by either Party to the other of any right, title, license or other interest of any kind in any of its Intellectual Property Rights, (b) creating an obligation on the part of either Party to make any such grant, transfer or other conveyance or (c) requiring either Party to participate with the other Party in any cooperative development program or project of any kind or to continue with any such program or project. Nothing in this Agreement shall modify, or be deemed to modify, the allocation of ownership, and corresponding rights and licenses granted between the Parties, under the License Agreements, with respect to any Intellectual Property Rights and/or inventions thereunder.

21. MISCELLANEOUS

21.1 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, acts of governments, revolution, acts of terror, fire, earthquake, flood, pestilence, riot, accident(s), 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 [***], the Parties shall meet and work diligently to implement appropriate remedial measures.

21.2 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.

21.3 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. Except as expressly set forth in this Agreement [***], all rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be a limitation of any other remedy, right, undertaking, obligation or agreement.

21.4 Entire Agreements; Amendments. This Agreement, together with the Product Schedules, and the QA, 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 Customer and Supplier before the date hereof with respect to the subject matter hereof. None of the terms of this Agreement shall be amended, supplemented or modified except in writing signed by the Parties.

21.5 Survival. The provisions that are expressly designated as those that survive the expiration or termination of this Agreement, the provisions of Articles 2, 15, 17, 19, 21 and Sections 8.4, 13.9 and 13.10 with respect to deemed Triggering Events, 13.11 and 18.5, as well as any other Sections or defined terms referred to in such Sections or necessary to give them effect, shall survive termination of this Agreement and remain in force until discharged in full.

21.6 Assignment; Binding Effect.

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

(b) Any purported assignment in violation of this Section 21.6 shall be void. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

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

21.8 Notices. Each communication and document made or delivered by one Party to another under this Agreement shall be made in the English language. All notices, consents, approvals, requests or other communications required hereunder given by one Party to the other hereunder shall be in writing and made by registered or certified air mail, facsimile, express overnight courier or delivered personally to the following addresses of the respective Parties:

If to Customer:

Dror Bashan
P.O. Box 455,
Karmiel 2161401, Israel

with a copy to:

Eyal Rubin

If to Supplier:

Chief Executive Officer
Via Palermo 26/A,
Parma, 43122 Italy

with a copy to:

General Counsel; and
Head of Global Corporate Development

Notices hereunder shall be deemed to be effective (a) upon receipt if personally delivered, (b) on the tenth (10th) Business Day following the date of mailing if sent

by registered or certified air mail and (c) on the second (2nd) Business Day following the date of transmission or delivery to the overnight courier if sent by facsimile or overnight courier. A Party may change its address listed above by sending notice to the other Party in accordance with this Section 21.8.

21.9 Third-Party Beneficiaries. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party. No Third Party shall obtain any right under any provision of this Agreement or shall by reason of any such provision make any claim in respect of any debt, liability or obligation (or otherwise) against either Party.

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

21.11 Counterparts. This Agreement may be executed in any number of counterparts (including via digital or electronic signature), each of which, when executed, shall be deemed to be an original and which together shall constitute one and the same document. Signatures provided by facsimile transmission or in electronic format shall be deemed to be original signatures.

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

21.13 Equitable Remedies. The Parties agree that irreparable damage may occur in the event that a Party breaches Articles 15 or 20 of this Agreement. 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 as a result of breaches of Articles 15 or 20 of this Agreement and to enforce specifically the terms and provisions of Articles 15 or 20 of this Agreement.

[Signature Page Follows]

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

CHIESI FARMACEUTICI S.p.A.

By: /s/ Alberto Chiesi

Name: Alberto Chiesi

Title: President

CHIESI FARMACEUTICI S.p.A.

By: /s/ Ugo Di Francesco

Name: Ugo Di Francesco

Title: Chief Executive Officer

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

PROTALIX LTD.

By: /s/ Dror Bashan
Name: Dror Bashan
Title: President and Chief Executive Officer

PROTALIX LTD.

By: /s/ Eyal Rubin
Name: Eyal Rubin
Title: Sr. Vice President and Chief Financial Officer

Exhibit 1

Product Schedule for FILL/FINISH of Pegunigalsidase Alfa Vials

[***]

Exhibit 2

Quality Agreement

[***]

Exhibit 3

Tech Transfer Plan

[***]

Exhibit 10.2

CONFIDENTIAL *EXECUTION VERSION*

Certain confidential portions of this exhibit have been omitted and replaced with "[***]". Such identified information has been excluded from this exhibit because it is both not material and is the type that the registrant treats as private or confidential.

Via Palermo 26/A,
Parma, 43122 Italy

August 29, 2022

Dror Bashan
President and Chief Executive Officer
Protalix Ltd.
2 Snunit Street, Science Park
P.O. Box 455
Karmiel 2161401, Israel

Re: Additional Matters Related to the Fill/Finish Agreement and License Agreements

Dear Dror:

Protalix Ltd. ("Protalix") and Chiesi Farmaceutici S.p.A. ("Chiesi") are parties to (a) that certain Exclusive License and Supply Agreement dated October 17, 2017 (the "Ex-US License Agreement"); and (b) that certain Exclusive U.S. License and Supply Agreement dated July 23, 2018 (the "US License Agreement") ((a) and (b), collectively, the "License Agreements," and each, a "License Agreement"), pursuant to which Protalix granted to Chiesi, among other rights, an exclusive license to certain Intellectual Property Rights with respect to the commercialization of the Licensed Product worldwide (as such terms are defined in the applicable License Agreement). In addition, Protalix and Chiesi have entered into that certain Fill/Finish Agreement contemporaneously herewith dated August 29, 2022 (the "Fill/Finish Agreement"), pursuant to which Protalix appoints Chiesi to perform, and Chiesi agrees to perform, Fill/Finish (as used throughout this Agreement (defined below)), (i) in the context of the Fill/Finish Agreement, as defined in the Fill/Finish Agreement, and (ii) in the context of the License Agreement(s), as defined in the applicable License Agreement) supply services for Protalix and Protalix agrees to supply Drug Substance to Chiesi for such purposes, thereunder.

By signing this letter agreement (this "Agreement") below, Chiesi and Protalix each hereby agree as follows:

1. (a) With the express intent of modifying their obligations under Section 4.13 of the License Agreements solely with respect to the Selected CMO, [***], pursuant to Section 15.4 of the License Agreements, Chiesi and Protalix each hereby agree as set forth in this Section 1.

(b) Promptly, but in any event within [***] following execution of this Agreement, Protalix will nominate (i.e., provide to Chiesi the name (and proposed site(s) and lines) of) [***] third party tier 1 fill/finish contract manufacturing organizations (that Protalix reasonably believes would be suitable candidates for Fill/Finish of Drug Product) for inclusion as potential alternate/secondary source candidates for the Fill/Finish of Drug Product under the License Agreements (each a "CMO Candidate") and provide Chiesi with a copy of the formal quote (which may be [***]) therefor (and any updates thereto) from each CMO Candidate. [***].

(c) The first CMO Candidate proposed by Protalix would be jointly evaluated in good faith by the Parties for suitability and reliability, including, without limitation, customary quality audit, technical evaluation of equipment and financial evaluation (each consistent with such party's customary practices and procedures), within [***] following the Effective Date (as defined in the Fill/Finish Agreement) that is [***], provided that, for the avoidance of doubt, [***] would be considered a Pre-Approved CMO (as defined below) [***], each conducted in good faith by the parties hereunder in accordance with their customary practices and procedures. Protalix and Chiesi would each bear their own costs in performing such nominations, evaluations and selection.

(d) Each CMO Candidate which both (i) has submitted a quote to Protalix (with a copy provided by Protalix to Chiesi pursuant to clause (b) above) and (ii) is determined [***] as a result of the above evaluations, would constitute a pre-approved Fill/Finish alternative source (each a "Pre-Approved CMO") (the date of such pre-approval, "CMO Candidate Pre-Approval Date"). For clarity, pre-approval for each Pre-Approved CMO shall apply only to the particular line(s)/facility(ies) of such Pre-Approved CMO for Fill/Finish of Drug Product that were evaluated by the parties and determined to be [***], and not to other lines/facilities thereof that were not the subject of evaluation or determined not to be [***]. The pre-approval or rejection of each CMO Candidate shall be documented [***] in a written notice (signed by an authorized representative of such party) provided to [***].

(e) In the event that the foregoing initial evaluation process does not result in a Pre-Approved CMO (the date of such event, the "CMO Candidate Rejection Date"), the Parties shall promptly repeat the process described in clauses (c) through (d) above for the second CMO Candidate proposed by Protalix and, if applicable, the process described in clauses (b) through (d) above for each subsequent CMO Candidate proposed by Protalix, provided that (i) with respect to the second CMO Candidate proposed by Protalix, such [***] nomination period will be reduced to [***] measured from the CMO Candidate Rejection Date, and (ii) with respect to any subsequent CMO Candidate(s), Protalix and Chiesi must [***].

(f) No later than [***] from the CMO Candidate Pre-Approval Date, Protalix will begin to diligently negotiate (in a reasonable, good faith and customary manner consistent with industry market terms) with such Pre-Approved CMO (the "Selected CMO") the terms on which the Selected CMO will serve as an alternative source for Fill/Finish under the License Agreements. Upon completion of negotiations in a manner reasonably satisfactory to Protalix, consistent with the foregoing and compliant with the requirements of clause (g), enter into a definitive agreement with the Selected CMO (the effective date of such agreement, the "Selected CMO Agreement Date").

(g) From and after the selection of such Selected CMO as contemplated by clause (f) above, Protalix will diligently establish and Qualify (including, without limitation, in compliance with all applicable Law, GMP, Product Specifications and the then-current Regulatory Approvals (and as otherwise required by a Regulatory Authority) for the Licensed Product in the Territory (as each of the foregoing capitalized terms is defined in the applicable License Agreement)) such Selected CMO as an alternative source for Fill/Finish under the License Agreements, [***]. The terms "Qualify" or "Qualification" (and variations thereof) means to complete or completion of (as the context requires) [***], provided that the foregoing shall not limit, or be deemed to limit, Protalix's regulatory obligations under the License Agreements applicable to preparing, seeking and obtaining Regulatory Approvals or establishing or qualifying an alternative source of Fill/Finish, including, without limitation, Section 3.6(d)(iii) of each License Agreement and cooperating with Chiesi for same ("Protalix Regulatory Responsibilities"). With respect to such negotiations with such Selected CMO (as described in clause (f) above) and the corresponding establishment and Qualification thereof as an alternative source for Fill/Finish, as between the parties, Protalix will be responsible for such negotiations, establishment, and Qualification, provided that (x) the definitive agreement with such Selected CMO must be consistent with the requirements of the License Agreements, and (y) Protalix will provide Chiesi, until completion thereof, regular [***] updates,

through Protalix's and Chiesi's respective operational teams, with respect to the progress/status of such negotiations, establishment and Qualification, and the Parties agree to discuss accordingly.

(h) From and after [***], Chiesi will [***] after receiving from Protalix the [***]. As between the Parties, Chiesi will be responsible (subject to, and without limiting, Protalix's performance of the Protalix Regulatory Responsibilities in accordance with the License Agreements) for [***], provided that Chiesi will provide Protalix, until completion thereof, regular [***] updates, through Protalix's and Chiesi's respective operational teams, with respect to the progress/status of such [***], and the Parties agree to discuss accordingly. Upon establishment and Qualification of such Selected CMO as contemplated hereunder, and completion of the [***], the applicable Selected CMO shall constitute the Initial Alternate Source (as defined in the Fill/Finish Agreement). For the avoidance of doubt, [***].

(i) With the express intent of modifying their obligations under Section 4.13 of the License Agreements solely with respect to such Selected CMO, pursuant to Section 15.4 thereof, [***]. Protalix shall (a) promptly (upon Protalix's receipt thereof) provide to Chiesi a copy of the Selected CMO's invoice submitted pursuant to such definitive agreement, and, (b) promptly upon the payment due date for such invoice thereunder, provide Chiesi either a written confirmation of its accuracy, or written final corrections to such invoice and upon a reasonable written request of Chiesi, use Commercially Reasonable Efforts to provide reasonable supporting documentation for the same, including, without limitation, as provided by the Selected CMO) therefor, provided that (x) [***], (y) [***], and (z) [***].

(j) [***].

2. [***]

3. In accordance with Section 15.4 thereof, the following definitions are hereby added, in the appropriate alphabetical order, to Article 1 in both License Agreements:

> ""Fill/Finish CMO Agreement" means (i) the [***] Agreement; and (ii) any other agreement between a Fill/Finish CMO, other than Chiesi or [***], and Protalix with respect to the performance of Fill/Finish services."
>
> ""Fill/Finish CMO" means (i) [***], (ii) Sections 4.2(a)(i)(solely as the identified recipient of Drug Substance required to be delivered by Protalix), 4.7(b) (for (i) and for last sentence only), 4.12(b)(ii) and 6.7(a) of the License Agreements, Chiesi, or any of its Affiliates, and (iii) any Third Party, or any of its Affiliates, in each case, (i) – (iii), to the extent such Person is performing Fill/Finish services under contract to Protalix."

4. In accordance with Section 15.4 thereof, each instance of "[***]" in (a) Sections 1.49, 4.2(a), 4.7(b), 4.12(b)(ii) and 6.7(a) of the Ex-US License Agreement, and (b) Sections 1.55, 4.2(a), 4.7(b), 4.12(b)(ii) and 6.7(a) of the US License Agreement, is hereby deleted in its entirety from such License Agreement and replaced with "Fill/Finish CMO".

5. In accordance with Section 15.4 thereof, each instance of "[***] Agreement" in Sections 4.2(a) of each License Agreement is hereby deleted in its entirety from such License Agreements and replaced with "Fill/Finish CMO Agreement."

6. [***], the Parties acknowledge that [***] (each, as defined in the applicable License Agreement) that Protalix is required [***] under the License Agreements, and [***].

7. Except as expressly contemplated herein, this Agreement shall not be construed to otherwise modify, waive, impair or affect any other terms, provisions or conditions of the License Agreements or Fill/Finish Agreement. For the avoidance of doubt, Chiesi and Protalix each do not release the other Party or any third party (including, without limitation, [***]) from any obligations, including, without limitation, any obligations expressly created by this Agreement or any obligations, rights or claims arising under the License Agreements, [***] Agreement or Fill/Finish Agreement, all of which are hereby expressly preserved.

8. This Agreement will be governed by and construed in accordance with the substantive laws of the State of New York, without regard to conflicts of law rules. The provisions of the U.N. Convention on Contracts for the International Sale of Goods will not apply to this Agreement. No amendment, modification or waiver of any term or condition of this Agreement will be effective unless in writing and signed by both parties.

9. This Agreement may be executed in any number of counterparts (including, without limitation, via digital or electronic signature), each of which, when executed, shall be deemed to be an original and which together shall constitute one and the same document. Signatures provided by facsimile transmission or in electronic format shall be deemed to be original signatures.

[Signature Page Follows]

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

CHIESI FARMACEUTICI S.p.A.

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

CHIESI FARMACEUTICI S.p.A.

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

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

PROTALIX LTD.

By: /s/ Dror Bashan
Name: Dror Bashan
Title: President and
Chief Executive Officer

PROTALIX LTD.

By: /s/ Eyal Rubin
Name: Eyal Rubin
Title: Sr. Vice President and
Chief Financial Officer

EXHIBIT 31.1

CERTIFICATION

I, Dror Bashan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2022

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

EXHIBIT 31.2

CERTIFICATION

I, Eyal Rubin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 14, 2022

/s/ Eyal Rubin
Eyal Rubin
Sr. Vice President & Chief Financial Officer,
Treasurer

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Dror Bashan, President and Chief Executive Officer of the Company, hereby certify as of the date hereof, solely for purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

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

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

Date: November 14, 2022

/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, 2022 as filed with the Securities and Exchange Commission (the "Report"), I, Eyal Rubin, Senior Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

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

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

Date: November 14, 2022

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