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 June 30, 2023

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 August 1, 2023, approximately 71,580,762 shares of the Registrant's common stock, $0.001 par value, were outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 48,184	$ 17,111
Short-term bank deposits	—	5,069
Accounts receivable – Trade	4,049	4,586
Other assets	1,708	1,310
Inventories	19,635	16,804
Total current assets	$ 73,576	$ 44,880
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,268	$ 1,267
Property and equipment, net	4,637	4,553
Deferred income tax asset	3,130	—
Operating lease right of use assets	5,806	5,087
Total assets	$ 88,417	$ 55,787
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,304	$ 5,862
Other	18,545	12,271
Operating lease liabilities	1,260	1,118
Contracts liability	—	13,178
Total current liabilities	$ 23,109	$ 32,429
LONG TERM LIABILITIES:		
Convertible notes	$ 20,132	$ 28,187
Liability for employee rights upon retirement	1,598	1,642
Operating lease liabilities	4,577	4,169
Total long term liabilities	$ 26,307	$ 33,998
Total liabilities	$ 49,416	$ 66,427
COMMITMENTS		
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)	39,001	(10,640)
Total liabilities and stockholders' equity (net of capital deficiency)	$ 88,417	$ 55,787

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)

	Six Months Ended		Three Months Ended	
	June 30, 2023	June 30, 2022	June 30, 2023	June 30, 2022
REVENUES FROM SELLING GOODS	$ 20,141	$ 12,410	$ 15,075	$ 3,382
REVENUES FROM LICENSE AND R&D SERVICES	24,522	12,428	20,000	5,371
TOTAL REVENUE	44,663	24,838	35,075	8,753
COST OF GOODS SOLD (1)	(9,233)	(10,121)	(6,148)	(4,087)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(10,322)	(16,346)	(4,475)	(7,579)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(7,146)	(5,765)	(4,031)	(2,611)
OPERATING INCOME (LOSS)	17,962	(7,394)	20,421	(5,524)
FINANCIAL EXPENSES	(2,169)	(1,242)	(1,305)	(623)
FINANCIAL INCOME	918	1,016	531	813
FINANCIAL INCOME (EXPENSES), NET	(1,251)	(226)	(774)	190
INCOME (LOSS) BEFORE TAXES ON INCOME	16,711	(7,620)	19,647	(5,334)
TAXES ON INCOME	(503)	-	(308)	-
NET INCOME (LOSS) FOR THE PERIOD	$ 16,208	$ (7,620)	$ 19,339	$ (5,334)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ 0.26	$ (0.16)	$ 0.29	$ (0.11)
DILUTED	$ 0.18	$ (0.16)	$ 0.21	$ (0.11)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	62,378,745	46,589,976	67,158,628	47,327,952
DILUTED	78,896,220	46,589,976	83,200,641	47,327,952
(1) Includes share-based compensation	$ 104	$ 22	$ 46	$ 28
(2) Includes share-based compensation	$ 324	$ 161	$ 144	$ 85
(3) Includes share-based compensation	$ 556	$ 941	$ 248	$ 175

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, 2022	**45,556,647**	**$ 46**	**$ 368,852**	**$ (374,934)**	**$ (6,036)**
Changes during the six-month period ended June 30, 2022:					
Issuance of common stock under the Sales Agreement, net	2,395,823	3	2,638		2,641
Share-based compensation related to stock options			293		293
Share-based compensation related to restricted stock awards	759,482	*	831		831
Exercise of warrants	1,000	*	2		2
Net loss for the period				(7,620)	(7,620)
Balance at June 30, 2022	**48,712,952**	**$ 49**	**$ 372,616**	**$ (382,554)**	**$ (9,889)**
Balance at January 1, 2023	**53,790,167**	**$ 54**	**$ 379,167**	**$ (389,861)**	**$ (10,640)**
Changes during the six-month period ended June 30, 2023:					
Issuance of common stock under the Sales Agreement, net	12,560,150	13	23,941		23,954
Convertible notes conversions	4,691,623	5	7,778		7,783
Share-based compensation related to stock options			812		812
Share-based compensation related to restricted stock awards			172		172
Exercise of warrants	538,822	*	712		712
Net income for the period				16,208	16,208
Balance at June 30, 2023	**71,580,762**	**$ 72**	**$ 412,582**	**$ (373,653)**	**$ 39,001**
Balance at March 31, 2022	**46,316,129**	**$ 46**	**$ 369,688**	**$ (377,220)**	**$ (7,486)**
Changes during the three-month period ended June 30, 2022:					
Issuance of common stock under the Sales Agreement, net	2,395,823	3	2,638		2,641
Share-based compensation related to stock options			144		144
Share-based compensation related to restricted stock awards			144		144
Exercise of warrants	1,000	*	2		2
Net loss for the period				(5,334)	(5,334)
Balance at June 30, 2022	**48,712,952**	**$ 49**	**$ 372,616**	**$ (382,554)**	**$ (9,889)**
Balance at March 31, 2023	**62,002,649**	**$ 62**	**$ 393,938**	**$ (392,992)**	**$ 1,008**
Changes during the three-month period ended June 30, 2023:					
Issuance of common stock under the Sales Agreement, net	4,347,668	5	9,716		9,721
Convertible notes conversions	4,691,623	5	7,778		7,783
Share-based compensation related to stock options			359		359
Share-based compensation related to restricted stock awards			79		79
Exercise of warrants	538,822	*	712		712
Net income for the period				19,339	19,339
Balance at June 30, 2023	**71,580,762**	**$ 72**	**$ 412,582**	**$ (373,653)**	**$ 39,001**

*Represents an amount equal to less than $1.

(1) Common stock, $0.001 par value; Authorized – as of June 30, 2023 and 2022 – 144,000,000 shares.

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

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

	Six Months Ended	
	June 30, 2023	June 30, 2022
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 16,208	$ (7,620)
Adjustments required to reconcile net income (loss) to net cash used in operating activities:		
Share-based compensation	984	1,124
Depreciation	573	538
Financial income, net (mainly exchange differences)	(152)	(952)
Changes in accrued liability for employee rights upon retirement	36	(449)
Changes in deferred tax asset	(3,130)	
Loss (gain) on amounts funded in respect of employee rights upon retirement	(27)	16
Gain on conversions of convertible notes	(421)	
Amortization of debt issuance costs and debt discount	148	146
Changes in operating assets and liabilities:		
Decrease in contracts liability	(13,178)	(2,644)
Decrease in accounts receivable-trade and other assets	119	76
Changes in operating lease right of use assets, net	3	(3)
Decrease (increase) in inventories	(2,831)	1,447
Increase (decrease) in accounts payable and accruals	3,643	(4,864)
Net cash provided by (used in) operating activities	$ 1,975	$ (13,185)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in bank deposits		$ (16,000)
Proceeds from sale of short-term deposits	$ 5,000	
Purchase of property and equipment	(452)	(357)
Amounts paid (funded) in respect of employee rights upon retirement, net	(38)	457
Net cash provided by (used in) investing activities	$ 4,510	$ (15,900)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock under the Sales Agreement, net	$ 23,954	$ 2,641
Exercise of warrants	712	2
Net cash provided by financing activities	$ 24,666	$ 2,643
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (78)	$ (51)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	31,073	(26,493)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	17,111	38,985
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 48,184	$ 12,492

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

	Six Months Ended	
	June 30, 2023	June 30, 2022
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 348	$ 81
Operating lease right of use assets obtained in exchange for new operating lease liabilities	$ 1,079	$ 99
Convertible notes conversions	$ 7,783	$ —
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$ 1,977	$ 1,120
Interest received	$ 78	$ 93

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"). The Company's current focus is to facilitate the commercialization efforts of Chiesi Farmaceutici S.p.A. ("Chiesi"), the Company's development and commercialization partner for pegunigalsidase alfa, or Elfabrio® (which the Company referred to as PRX-102 during its development stage), for the treatment of Fabry disease, a rare, genetic lysosomal disorder. To date, the Company has successfully developed taliglucerase alfa (marketed under the name Elelyso® except in Brazil where it is marketed as BioManguinhos alfataliglicerase) for the treatment of Gaucher disease that has been approved for marketing in the United States, Brazil, Israel and other markets. The Company's strategy is to develop proprietary recombinant proteins designed to address high, unmet needs in the rare disease space that are therapeutically superior to existing recombinant proteins currently marketed for the same indications. Consistent with this strategy, the Company has a number of product candidates in varying stages of the clinical development process.

On May 5, 2023, the European Commission ("EC") announced that it had approved the Marketing Authorization Application ("MAA") for Elfabrio and on May 9, 2023, the U.S. Food and Drug Administration ("FDA") announced that it had approved the Biologics License Application ("BLA") for Elfabrio, each for adult patients with Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage. The European Medicines Agency ("EMA") approval followed the February 2023 adoption of a positive opinion and recommendation of marketing authorization for Elfabrio by the EMA's Committee for Medicinal Products for Human Use the ("CHMP"). Elfabrio was approved by the FDA with a boxed warning for hypersensitivity reactions/anaphylaxis, consistent with Enzyme Replacement Therapy (ERT) class labeling, and Warnings/Precautions providing guidance on the signs and symptoms of hypersensitivity and infusion-associated reactions seen in the clinical studies as well as treatments to manage such events should they occur. The Warnings/Precautions for membranoproliferative glomerulonephritis (MPGN) alert prescribers to the possibility of MPGN and provide guidance for appropriate patient management. Overall, the FDA review team concluded that in the context of Fabry disease as a rare, serious disease with limited therapeutic options that may not be suitable to all individual patients, the benefit-risk of Elfabrio is favorable for the treatment of adults with confirmed Fabry disease.

The Company has entered into two exclusive global licensing and supply agreements for Elfabrio with its development and commercialization partner for PRX-102, Chiesi Farmaceutici S.p.A. ("Chiesi"). On October 19, 2017, Protalix Ltd., the Company's wholly-owned subsidiary, entered into an Exclusive License and Supply Agreement with Chiesi (the "Chiesi Ex-US Agreement"), pursuant to which Chiesi was granted an exclusive license for all markets outside of the United States to commercialize Elfabrio. On July 23, 2018, Protalix Ltd. entered into an Exclusive License and Supply Agreement with Chiesi (the Chiesi US Agreement, with respect to the commercialization of Elfabrio in the United States.

Elfabrio, an enzyme replacement therapy, or ERT, was the subject of a phase III clinical program studying the drug as a treatment of patients with Fabry disease, a rare, genetic lysosomal disorder. The phase III clinical program included three separate studies, which are referred to as the *BALANCE* study, the *BRIDGE* study and the *BRIGHT* study. The phase III clinical program analyzed two potential dosing regimens: 1 mg/kg every two weeks and 2 mg/kg every four weeks. In addition, the phase III clinical program included two extension studies in which subjects that participated in our phase I/II clinical trials and phase III clinical trials had the opportunity to enroll and continue to be treated with PRX-102. As of March 1, 2023, sponsorship of the two open-label extension studies was transferred to Chiesi, which is now administering the extension studies. Currently, in the aggregate, 126 patients are enrolled, and 116 patients are actively participating, in such studies.

The BLA for Elfabrio for the treatment of adult patients with Fabry disease was resubmitted to the FDA on November 9, 2022. An initial BLA for Elfabrio was submitted to the FDA on May 27, 2020 under the FDA's Accelerated Approval pathway, but resulted in a Complete Response Letter ("CRL").

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The MAA was submitted to the EMA on February 7, 2022, after the October 8, 2021 meeting we held, together with Chiesi, with the Rapporteur and Co-Rapporteur of the EMA regarding PRX-102.

The FDA publicly released the internal review documents for Elfabrio (pegunigalsidase alfa-iwxj) injection BLA 761161. These documents provide previously unavailable additional information regarding the basis for the FDA's May 2023 approval decision. In particular, the FDA determined that substantial evidence of effectiveness for Elfabrio in Fabry patients was established with one adequate and well-controlled study (Study PB-102-F01/02) with confirmatory evidence provided by the *BALANCE* study (also referred to as Study PB-102-F20). The FDA review team also concluded that the *BALANCE* study met its primary efficacy endpoint, which assessed the annualized rate of change in eGFR (estimated glomerular filtration rate) over 104 weeks. However, the FDA also determined that the results from the *BALANCE* study did not support a non-inferiority claim to the comparator product due to the lack of data to support a non-inferiority margin.

In addition to Elfabrio, the Company successfully developed taliglucerase alfa, an enzyme replacement therapy for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease, that has been approved for marketing in the United States, Brazil, Israel and other markets.

The Company has licensed the rights to commercialize taliglucerase alfa worldwide (other than Brazil) to Pfizer Inc. ("Pfizer"), and in Brazil to Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health (the "Brazilian MoH"). Otherwise, except with respect to taliglucerase alfa and Elfabrio, the Company holds the worldwide commercialization rights to its other proprietary development candidates. In addition, the Company continuously evaluates potential strategic marketing partnerships as well as collaboration programs with biotechnology and pharmaceutical companies and academic research institutions.

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

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

(2) 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.

On March 21, 2023, the first patient was dosed in the Company's phase I First in Human ("FIH") clinical trial of PRX-115. As of the date hereof, 13 patients have been dosed in this trial.

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

On July 2, 2021, the Company entered into an At The Market Offering Agreement (the "2021 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 2021 Sales Agreement, the Company was able to 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 2021 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.

During the term of the 2021 Sales Agreement which ended during the quarter ended March 31, 2023, the Company sold a total of 13,980,060 ATM Shares for total gross proceeds of approximately $20.0 million under the 2021 Sales Agreement, thereby completing the ATM program under said agreement.

On February 27, 2023, the Company entered into an At The Market Offering Agreement (the "2023 Sales Agreement") with the Agent. Pursuant to the terms of the 2023 Sales Agreement, the Company may sell, from time to time through

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

the Agent, ATM Shares having an aggregate offering price of up to $20.0 million. As of June 30, 2023, shares of Common Stock for total gross proceeds of approximately $6.4 million remain available to be sold under the 2023 Sales Agreement.

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 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 and to receive additional payments of up to a maximum of $760.0 million, in the aggregate, in regulatory and commercial milestone payments. To date, Protalix Ltd. has received the complete amount of development costs to which it is entitled under the Chiesi Agreements. In addition, following the approval of Elfabrio by the FDA, the Company received a milestone payment equal to $20.0 million.

Under the terms of both of the Chiesi Agreements, Protalix Ltd. is required to manufacture all of the Elfabrio drug substance needed under the agreements, subject to certain exceptions, and Chiesi will purchase Elfabrio drug substance 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 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.

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. Chiesi agreed to make a $10.0 million payment to the Company 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. The Company received the payment in June 2021. The Company also agreed to negotiate certain manufacturing related matters.

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

On June 18, 2013, the Company entered into a Supply and Technology Transfer Agreement with Fiocruz (the "Brazil Agreement") 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 Company expects to continue to incur significant expenditures in the near future due to research and developments efforts with respect to the product candidates. Under the terms of the Company's outstanding 7.50% Senior Secured

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

Convertible Notes due 2024 (the "2024 Notes"), the Company is required to comply with certain financial covenants, including the maintenance of a minimum cash balance of at least $7.5 million. As of June 30, 2023, the Company is in compliance with all such covenants. The Company believes that its cash and cash equivalents as of June 30, 2023, are sufficient to satisfy the Company's capital needs for at least 12 months from the date that these financial statements are issued.

b. Basis of presentation

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

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, 2022, filed by the Company with the U.S. Securities and Exchange Commission (the "Commission"). The comparative balance sheet at December 31, 2022 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, 2022.

c. 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), at the net selling price, which reflects reserves for variable consideration, potential discounts and allowances.

   The transaction price is the consideration to which the Company expects to be entitled from the customer. The consideration promised in a contract with the Company's customers may include fixed amounts and variable amounts. The Company estimates the variable consideration and includes it in the transaction price using the most likely outcome method, and only to the extent it is highly probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Prior to recognizing revenue from variable consideration, the Company uses significant judgment to determine the probability of significant reversal of such revenue.

2. Revenues from Chiesi Agreements

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

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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 manufacturing was 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, research and development services. Following the regulatory approvals for Elfabrio received in May 2023, the Company started recognizing revenue from manufacturing, see also revenue from selling products above.

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. Following the approval of Elfabrio by the FDA, the Company received a milestone payment equal to $20.0 million (see also note 4).

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 was recognized over time using the cost-to-cost method.

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

3. Revenue from R&D services

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

NOTE 2 - INVENTORIES

Inventories at June 30, 2023 and December 31, 2022 consisted of the following:

(*U.S. dollars in thousands*)	June 30, 2023	December 31, 2022
Raw materials	$ 4,352	$ 3,508
Work in progress	3,318	2,678
Finished goods	11,965	10,618
Total inventory	$ 19,635	$ 16,804

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.

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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.

Based on a Level 3 measurement, as of June 30, 2023, the fair value of the $20.4 million aggregate principal amount of the Company's outstanding 2024 Notes is approximately $28.1 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)	2.00
Expected term	1.18
Risk free rate	5.14 %
Volatility	60.90 %
Yield	12.76 %

NOTE 4 – REVENUES

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

(U.S. dollars in thousands)	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Pfizer	$ 3,402	$ 3,382	$ 5,668	$ 6,738
Brazil	$ —	$ —	$ 2,800	$ 5,454
Chiesi	$ 11,673	$ —	$ 11,673	$ 218
Total revenues from selling goods	$ 15,075	$ 3,382	$ 20,141	$ 12,410
Revenues from license and R&D services	$ 20,000	$ 5,371	$ 24,522	$ 12,428

NOTE 5 – STOCK TRANSACTIONS

(a) Authorized Capital

On June 28, 2023, the Company held its 2023 Annual Meeting of Stockholders, which was adjourned and reconvened on July 13, 2023 (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 144,000,000 to 185,000,000 (the "Charter Amendment"). The Charter Amendment was filed with the Secretary of State of the State of Delaware on July 25, 2023.

(b) At-the-Market (ATM) Offering

During the six months ended June 30, 2023, the Company sold, in the aggregate, 12,560,150 shares of Common Stock under the 2023 Sales Agreement. The Company generated aggregate gross proceeds equal to approximately $24.9 million in connection with such sales.

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(c) Exercise of Warrants

On May 8, 2023, the Company issued 301,810 shares of Common Stock in connection with the cash exercise of a warrant issued on March 18, 2020, as part of the Company's private placement of Common Stock and warrants. The Company generated net proceeds equal to $0.7 million from the exercise of the warrant.

On May 10, 2023, the Company issued 237,012 shares of Common Stock in connection with the cashless exercise of a warrant to purchase 845,000 shares of Common Stock issued on March 18, 2020, as part of the Company's private placement of Common Stock and warrants. The Company did not generate any proceeds from the cashless exercise.

(d) Conversion of 2024 Notes

During the six months ended June 30, 2023, the Company issued, in the aggregate, 4,691,623 shares of Common Stock in connection with the conversions of 2024 Notes. In connection with such conversions, during the six months ended June 30, 2023, the Company paid to the converting holders $0.9 million representing cash payments due to accrued but unpaid interest, make-whole interest payments and payments in lieu of fractional shares. As a result of the conversions, the total principal amount of the 2024 Notes decreased by approximately $8.3 million.

NOTE 6 – EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is calculated by dividing the net income (loss) by the weighted average number of shares of the Company's Common Stock outstanding during each period.

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

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except share and per share data)	2023	2022	2023	2022
Numerator:				
Net income (loss)	$ 19,339	$ (5,334)	$ 16,208	$ (7,620)
Add:				
Financial expenses of 2024 Notes*	$ (1,749)	—	$ (2,053)	—
Net income (loss) for diluted calculation	$ 17,590	$ (5,334)	$ 14,155	$ (7,620)
Denominator:				
Weighted average shares of Common Stock outstanding for basic calculation	67,158,628	47,327,952	62,378,745	46,589,976
Weighted average dilutive effect of 2024 Notes	14,355,621	—	15,274,121	—
Weighted average dilutive effect of stock options	1,555,307	—	1,243,354	—
Weighted average dilutive effect of warrants	131,085	—	—	—
Weighted average shares of Common Stock outstanding for diluted calculation	83,200,641	47,327,952	78,896,220	46,589,976

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

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Diluted earnings (loss) per share do not include 16,158,086 shares of Common Stock underlying outstanding stock options and warrants of the Company for the six months ended June 30, 2023 because the effect would be anti-dilutive.

Diluted earnings (loss) per share do not include 1,896,733 shares of Common Stock underlying outstanding stock options of the Company for the three months ended June 30, 2023 because the effect would be anti-dilutive.

Diluted earnings (loss) per share do not include 32,960,732 and 32,982,043 shares of Common Stock underlying outstanding stock options, warrants and the 2024 Notes for the three and six months ended June 30, 2022, respectively, because the effect would be anti-dilutive.

NOTE 7 – TAXES ON INCOME

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

(U.S. dollars in thousands)	Three Months Ended June 30, 2023	Six Months Ended June 30, 2023
Current taxes on income	$ 3,438	$ 3,633
Deferred taxes on income	(3,130)	(3,130)
Total taxes on income	$ 308	$ 503

The Company had an effective tax rate of 3% for the six months ended June 30, 2023, compared to an effective tax rate of 0% for the six months ended June 30, 2022. For the six months ended June 30, 2023, the difference between the Company's effective tax rate and the U.S. federal statutory rate of 21% was the result of the provision for current taxes on income mainly derived from U.S. taxable GILTI income mainly in respect of milestone payments and Section 174 of the U.S. Tax Cuts and Jobs Act, which was enacted in December 2017 (the "TCJA"), partially offset by the release of the valuation allowance on net operating losses (NOLs) in the United States.

In the second quarter ended June 30, 2023, following the regulatory approvals for Elfabrio in May 2023, the receipt of the $20.0 million milestone payment and the launch of Elfabrio in the United States, the Company released valuation allowance previously recorded on deferred tax assets in respect of its NOLs in the United States resulting in a net tax benefit of $3.1 million. The Company concluded that, based upon the preponderance of positive evidence over negative evidence and the anticipated ability to use the deferred tax assets, it was more likely than not that these deferred tax assets would be realizable due to forecasted profits. The Company considered the following: (i) cumulative profits for tax over the previous 12 quarters in its U.S. operations; (ii) the impact of Section 174 of the TCJA which requires the Company to capitalize and amortize its research and development expenses over 15 years; and (iii) its forecasted profits in the United States following the regulatory approvals of Elfabrio.

NOTE 8 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Balance sheets:

(U.S. dollars in thousands)	June 30, 2023	December 31, 2022
Accounts payable and accruals – other:		
Payroll and related expenses	$ 1,223	$ 1,216
Interest Payable	506	719
Provision for vacation	1,526	1,404
Accrued expenses	8,608	7,478
Royalties payable	1,262	781
Income tax payable	3,163	530
Reserve for deductions from revenue	1,909	—
Property and equipment suppliers	348	143
	$ 18,545	$ 12,271

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NOTE 9 – SUBSEQUENT EVENTS

On July 14, 2023, the Company collected approximately $1.1 million, in the aggregate, from sales to Pfizer. On July 7, 2023, the Company collected approximately $1.0 million from 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, 2022. 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:

- risks related to the commercialization of Elfabrio, our approved product for the treatment of adult patients with Fabry disease;

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

- risks related to our commercialization partner's ability to obtain and maintain reimbursement for Elfabrio, and the extent to which patient assistance programs and co-pay programs are utilized;

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

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

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

- delays in the approval or potential rejection of any applications we file with the FDA, EMA or other health regulatory authorities for our other product candidates, and other risks relating to the review process;

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

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

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

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

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

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

- risks related to the amount and sufficiency of our cash and cash equivalents;

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

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

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

- 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;

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

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

- the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;

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

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

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

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

- 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.

Given these uncertainties, you should not place undue reliance on these forward-looking statements. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or preliminary findings for such clinical trials. Even if favorable testing data is generated from clinical trials of a drug product, the FDA or foreign regulatory authorities may not accept or approve a marketing application filed by a pharmaceutical or biotechnology company for the drug product.

Recent Company Developments

- On May 5, 2023, we announced that the EC had granted marketing authorization to Elfabrio in the European Union for the treatment of adult patients with Fabry disease.

- On May 10, 2023, we announced that the FDA had approved Elfabrio (pegunigalsidase alfa-iwxj) in the United States for the treatment of adult patients with Fabry disease.

- On June 28, 2023, we held our Annual Meeting of Stockholders at which our stockholders: (1) elected the seven persons nominated by our Board of Directors to serve as directors of our Company; (2) approved, on a non-binding, advisory basis, the compensation of our named executive officers; (3) approved, on a non-binding, advisory basis, one year as the frequency at which

we will solicit stockholder approval of the compensation of our named executive officers; (4) adopted the amendments to our Amended and Restated 2006 Stock Incentive Plan, as amended, to increase the number of shares of common stock available under such plan from 8,475,171 shares to 12,475,171 shares and to amend certain other terms of the plan; and (5) ratified the appointment of Kesselman & Kesselman, Certified Public Accountants (Isr.), a member of PricewaterhouseCoopers International Limited, as our independent registered public accounting firm for the fiscal year ending December 31, 2023. The meeting was adjourned until July 13, 2023 to allow us to continue to solicit stockholder approval for the proposal to increase the amount of shares of common stock authorized for issuance under our Certificate of Incorporation, as amended, from 144,000,000 shares to 185,000,000 shares.

- On July 13, 2023, our stockholders approved an amendment to increase the amount of shares of common stock authorized for issuance under our Certificate of Incorporation, as amended from 144,000,000 shares to 185,000,000 shares. The Charter Amendment was filed with the Secretary of State of the State of Delaware on July 25, 2023.

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, and with the recent approval of Elfabrio, we now have two FDA approved proteins produced through our platform. 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

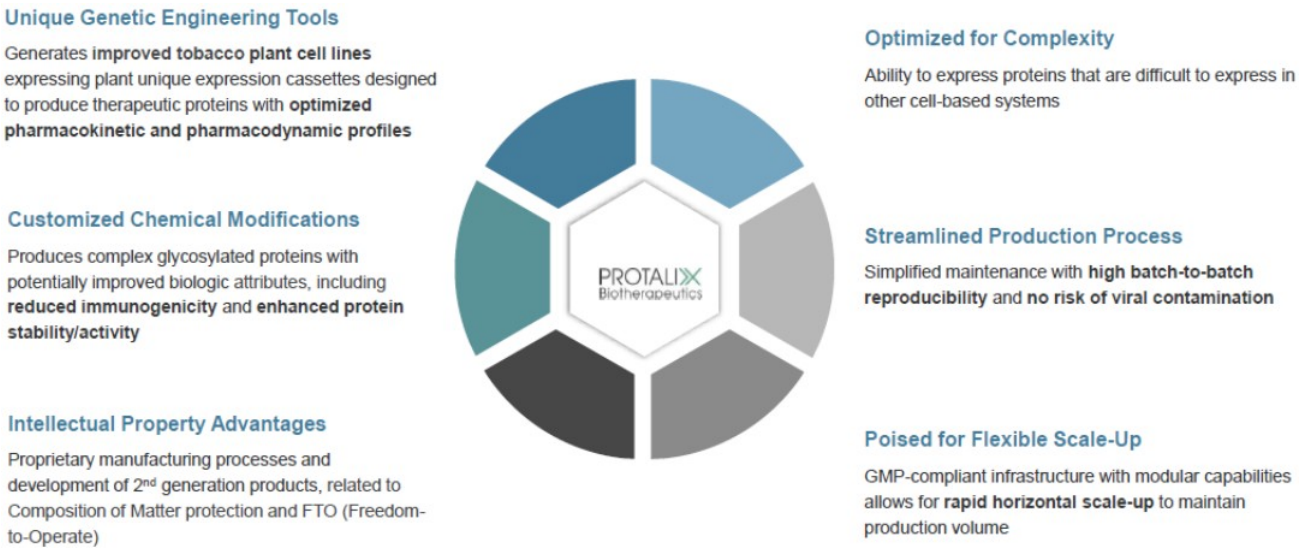
- High set-up costs involving large bioreactors
- Cell cultures require a complex medium; small changes in composition may affect product characteristics
- Require highly controlled growth conditions in the bioreactor (e.g., Ph., temp and CO_2)
- Susceptibility to viral contaminations

Bacteria and Yeast Cell Expression

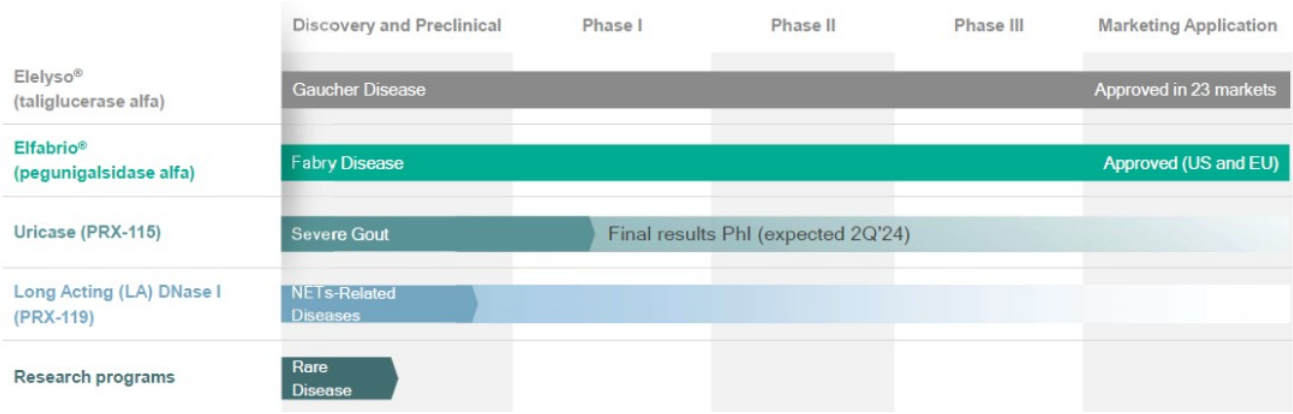
Bacteria or yeast cell lines

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

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



Products and Product Pipeline



Elfabrio (PRX-102) for the Treatment of Fabry Disease

On May 5, 2023, the EC announced that it had approved the MAA for Elfabrio and on May 9, 2023, the FDA announced that it had approved the BLA for Elfabrio, each for adult patients with Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage. The EMA approval followed the February 2023 adoption of a positive opinion and recommendation of marketing authorization for Elfabrio by the CHMP. Elfabrio was approved by the FDA with a boxed warning for hypersensitivity reactions/anaphylaxis, consistent with ERT class labeling, and Warnings/Precautions providing guidance on the signs and symptoms of hypersensitivity and infusion-associated reactions seen in the clinical studies as well as treatments to manage such events should they occur. The Warnings/Precautions for MPGN alert prescribers to the possibility of MPGN and provide guidance for appropriate patient management. Overall, the FDA review team concluded that in the context of Fabry disease as a rare, serious disease with limited therapeutic options that may not be suitable to all individual patients, the benefit-risk of Elfabrio is favorable for the treatment of adults with confirmed Fabry disease.

Elfabrio, an ERT, is our proprietary, plant cell culture expressed enzyme, and a chemically modified stabilized version of, the recombinant α-Galactosidase-A protein, a lysosomal enzyme. Fabry disease is a serious life-threatening rare genetic disorder. Fabry patients lack or have low levels of α-galactosidase-A resulting in the progressive accumulation of abnormal deposits of a fatty

substance called globotriaosylceramide, or Gb_3, in blood vessel walls throughout their body. The ultimate consequences of Gb_3 deposition range from episodes of pain and impaired peripheral sensation to end-organ failure, particularly of the kidneys, but also of the heart and the cerebrovascular system. Fabry disease occurs in one person per 40,000 to 60,000 males.

The global market for Fabry disease, that includes Sanofi's Fabrazyme®, Shire's (acquired by Takeda Pharmaceutical Company Limited) Replagal®, and Amicus Therapeutics' Galafold®, among others, was approximately $2.0 billion in 2022, is forecasted to be approximately $2.0 billion in 2023 and is forecasted to grow at a CAGR of approximately 13% from 2022-2028.

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. In 2015, we completed a phase I/II clinical trial of PRX-102, which 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. Our phase III clinical program, which has now been completed, included the following three separate studies:

The *BALANCE* study (PB-102-F20), a pivotal 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;

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

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

Patients who 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. Overall, 126 subjects who participated in our PRX-102 clinical program have opted, with the advice of the treating physician, to enroll in one of our long-term, open label, extension studies of PRX-102. 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 480 patient years (10 subjects who completed an extension study from the phase I/II study, 18 subjects who completed the *BRIDGE* study; 69 subjects who completed the *BALANCE* study), and 29 subjects who completed the *BRIGHT* study, in the 2 mg/kg every four weeks extension study (PB-102-F51) with a total cumulative exposure of approximately 145 patient years. Two of such subjects are being treated with 1 mg/kg every two weeks. As of March 1, 2023, sponsorship of the two extension studies was transferred to Chiesi, and Chiesi is now administering the open-label extension studies.

A BLA for Elfabrio for the treatment of adult patients with Fabry disease was first submitted to the FDA on May 27, 2020 under the FDA's Accelerated Approval pathway, but resulted in a CRL. The BLA was resubmitted to the FDA on November 9, 2022.

The MAA was submitted to the EMA on February 7, 2022, after the October 8, 2021 meeting we held, together with Chiesi, with the Rapporteur and Co-Rapporteur of the EMA regarding PRX-102.

The FDA publicly released the internal review documents for Elfabrio (pegunigalsidase alfa-iwxj) injection BLA 761161. These documents provide previously unavailable additional information regarding the basis for the FDA's May 2023 approval decision. In particular, the FDA determined that substantial evidence of effectiveness for Elfabrio in Fabry patients was established with one adequate and well-controlled study (Study PB-102-F01/02) with confirmatory evidence provided by the *BALANCE* study (also referred to as Study PB-102-F20). The FDA review team also concluded that the *BALANCE* study met its primary efficacy endpoint, which assessed the annualized rate of change in eGFR (estimated glomerular filtration rate) over 104 weeks.

However, the FDA also determined that the results from the *BALANCE* study did not support a non-inferiority claim to the comparator product due to the lack of data to support a non-inferiority margin.

In February 2020, we, together with Chiesi, announced an agreement with the FDA for the Initial Pediatric Study Plan (iPSP) for PRX-102, which is intended to be initiated post-marketing approval. 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.

Chiesi, together with Protalix, participated in an Oral Explanation at a meeting of the EMA's Committee for Orphan Medicinal Products (COMP) held on March 21, 2023, as part of the Orphan Drug Designation maintenance process. Following the meeting, Chiesi formally withdrew the application for Orphan Drug Designation for PRX-102. The EC first granted Orphan Drug Designation for PRX-102 for the treatment of Fabry disease in December 2017.

Phase III BALANCE Study

The Clinical Study Report for the *BALANCE* study was completed in July 2022. The final analysis confirmed the positive topline results (announced in April 2022) and favorable tolerability profile. A total of 78 patients who were previously treated with agalsidase beta for at least one year with an eGFR slope at screening worse than -2 mL/min/1.73 m^2/year were enrolled in the study. Patients were randomized on a 2:1 ratio for switching to PRX-102 or continuing on agalsidase beta. A total of 77 patients were treated; 52 with PRX-102 and 25 with agalsidase beta. Approximately 40% of the enrolled patients were female.

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.

Based on the original primary analysis (random intercept random slope (RIRS)), the estimated mean eGFR slopes were -2.4 mL/min/1.73 m^2 /year and -2.3 mL/min/1.73 m^2 /year in the PRX-102 and agalsidase beta arms, respectively, and the treatment difference was -0.1 (95% CI: -2.2, 2.1) mL/min/1.73 m^2 /year. Based on the ANCOVA adjusted for continuous baseline proteinuria, the estimated mean eGFR slopes were -2.0 and -3.1 mL/min/1.73 m^2 /year in the PRX-102 and agalsidase beta arms, respectively, and the treatment difference was 1.1 (95% CI: -0.8, 3.1) mL/min/1.73 m^2 /year. Based on quantile regression model, the median of the eGFR slope in the PRX-102 arm was -2.514 mL/min/1.73 m^2/year (95% CI:-3.788, -1.240) and -2.155 mL/min/1.73 m^2/year (95% CI:-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). Additional sensitivity and supportive analyses investigated mean eGFR slopes using other statistical models. These models yielded results similar to the primary analysis and confirming the comparability between the treatment arms. These results supported the robustness of the methodology used for comparisons of treatment effects in the *BALANCE* study. The results of the analyses on eGFR slopes were further supported by the analysis of change from baseline in the average eGFR at the last two visits (100 and 104 weeks). The estimated mean changes were -3.0 and -3.8 mL/min/1.73 m^2 in the PRX102 and agalsidase beta arms, respectively. The difference in mean change (PRX-102 – agalsidase beta) was 0.8 (95% CI: -3.0, 4.6) mL/min/1.73 m^2 or annualized change of 0.4 (95% CI: -1.5, 2.3) mL/min/1.73 m^2/year.

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/1.73 m^2 (20.32) and median eGFR was 74.51 ml/min/1.73 m^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/1.73 m^2/year.

A comparable efficacy response was also observed across biomarkers and functional systems relevant to Fabry disease, as demonstrated via secondary endpoints, where in some cases the trend was in favor of PRX-102 and in some in favor of agalsidase beta, but the actual difference between the two arms is always clinically small, supporting the comparability of the two treatments.

Key secondary endpoints included Urine protein creatinine ratio (UPCR) as indicator of proteinuria, plasma levels of lyso–Gb_3, imaging marker of cardiac remodeling (Left Ventricular Mass Index, LVMI, by cardiac MRI), disease severity (by Mainz Severity Score Index, MSSI), pain severity (Short Form Brief Pain Inventory, BPI) and quality of life (EQ-5D-5L). Both treatments showed either a stabilization of clinical parameters (e.g., for eGFR, eGFR slope and UPCR) or prevention of further progression of Fabry disease (e.g., LVMI, MSSI).

- *Secondary measures of kidney function*. In addition to eGFR levels and slope, the proportion of patients categorized as having severe proteinuria (UPCR ≥ 1 gr/gr) in the PRX-102 arm remained stable during the study (at baseline, 7/52 [13.5%] and 6/45 [13.3%] 24-month), while in the agalsidase beta arm, the proportion increased slightly with 3/25 (12.0%) and 4/24 (16.7%), respectively. Mean (SE) UPCR data (post-hoc analysis) for the entire study population remained stable throughout the study with a slight advantage for PRX-102 at 24-months compared to agalsidase beta (Table 1).

- *Biomarkers of Fabry disease*. Mean (SE) and median (range) plasma lyso-Gb_3 change from baseline to 24 months of treatment in the PRX-102 arm were 3.30 (1.38) and 1.15 (-32.2 to 32.7) nM for PRX-102, and -8.74 (4.85) and -1.50 (-102.3 to

2.4) nM for agalsidase beta. As expected, a gender difference was noted, with female Fabry patients exhibiting lower values at baseline and no remarkable changes during the study. Overall, the absolute changes of the Fabry biomarkers were minor in both treatment arms and were considered not clinically significant since there was no indication of Gb_3 re-accumulation nor of disease progression.

- *Measures of cardiac disease*. LVMi was centrally evaluated based on cardiac MRI. An increase in LVMi is indicative of progressing cardiomyopathy, hence preventing an increase in LVMI represents a therapeutic goal in Fabry patients. In the *BALANCE* study, the change from baseline in both treatment arms was analyzed by absence/presence of hypertrophy at baseline (defined as a LVMI above 91 g/m^2 for males and LVMI above 77 g/m^2 for females at baseline) and by gender (Kawel-Boehm 2015). Similar results were achieved in the two treatment arms after 24 months, with a slight reduction in the mean (SE) LVMi values in the PRX-102 arm -4.238 (5.731) and a small increase in the agalsidase beta arm 2.417 (9.620) for patients with hypertrophy at baseline. Small differences were observed also in those patients without hypertrophy at baseline in both treatment arms.

- *Measures of systemic disease burden (MSSI)*. Further evidence of the stabilization of the disease is provided by the MSSI overall scores, which remained stable throughout the *BALANCE* study in both arms, with the baseline score in both groups at the low end of the moderate range (means of 23.18 points in the PRX-102 arm and 25.16 points in the agalsidase beta arm), that slightly decreased (improvement by -2.1 points) in the PRX-102 arm and slightly increased in the agalsidase beta arm (+2.0 points). In this case, the CI of the difference in mean changes did not contain 0, suggesting a difference between the two arms in favor of PRX-102.

- *Patient reported outcomes*. With regards to the patient-reported outcomes (BPI and EQ-5D-5L), the two treatments showed very similar results, with the majority of patients reporting an improvement or no change in both groups, for each domain.

For an overview of primary and secondary endpoints collected in the *BALANCE* study, please refer to the Table 1 below.

Table 1: Summary Table of Comparison of Treatment Benefit Data in the *BALANCE* Study, (Mean (SE) [median]), Efficacy Population

Parameter		**PRX-102 (N = 52)**		**Agalsidase beta (N = 25)**	
eGFR ($ml/min/1.73\ m^2$)		**n**		**n**	
	Baseline	52	73.46 (2.80) [73.45]	25	74.16 (4.19) [74.85]
	Month 24	47	70.53 (3.19) [69.35]	24	72.05 (4.69) [74.48]
	Change from Baseline	47	-3.60 (1.58) [-2.39]	24	-1.97 (1.51) [-3.20]
eGFR slope ($ml/min/1.73\ m^2/yr$)	Baseline	52	-8.03 (0.92) [-6.70] Range: -30.5; 6.3	25	-8.25 (0.85) [-7.84] Range: -20.3; -2.8
	Month 24	51	-2.38 (1.25) [-2.51] Q1; Q3: -4.8; 0.8	25	-2.31 (0.71) [-2.16] Q1; Q3: -4.6; -0.5
Reaching kidney therapeutic goal[a]	Month 24	52	41 patients (80.4%)	25	20 patients (80.0%)
UPCR	Baseline	52	0.441 (0.084)	25	0.284 (0.097)
	Month 24	45	0.480 (0.118)	24	0.489 (0.162)
	Change from Baseline	45	0.088 (0.067)	24	0.197 (0.085)
Plasma lyso-Gb_3 (nM)	Baseline	52	26.22 (3.78) [15.20]	25	32.14 (7.08) [17.60]
	Month 24	46	29.22 (4.48) [18.80]	22	19.65 (3.60) [15.30]
	Change from Baseline	46	3.30 (1.38) [1.15]	22	-8.74 (4.85) [-1.50]
LVMI (g/m^2)	Baseline	40	75.97 (5.13)	22	82.22 (6.34)
	Month 24	35	71.56 (5.20)	20	82.43 (8.39)
	Change from Baseline	28	-0.64 (2.69)	19	0.29 (3.73)
MSSI (overall score)[a]	Baseline	49	23.18 (1.42)	25	25.16 (2.14)
	Month 24	46	22.11 (1.80)	23	27.09 (2.30)
	Change from Baseline	44	-2.07 (0.77)	23	2.04 (1.10)
BPI (score for pain at its worst)[b]	Baseline	52	3.5 (0.4)	25	2.6 (0.6)
	Month 24	45	3.3 (0.5)	22	3.0 (0.7)

	Change from Baseline	45	-0.1 (0.5)	22	0.6 (0.6)

BPI=brief pain inventory; eGFR=estimated glomerular filtration rate; lyso-Gb_3=globotriaosylsphingosine; LVMI=Left Ventricular Mass Index; MSSI=Mainz Severity Score Index; UPCR=Urine Protein Creatinine Ratio.

[a] Wanner 2018; [b] Higher scores indicate higher symptom severity.

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 the 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 who 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 who 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 which is now sponsored by Chiesi.

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

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

Phase III BRIDGE Study

The *BRIDGE* study was completed in December 2019. In the study, patients were screened and evaluated over three months while continuing agalsidase alfa treatment.

Final results of the data generated in the *BRIDGE* study showed substantial improvement in renal function as measured by mean annualized eGFR slope in both male and female patients. Twenty of 22 patients completed the 12-month treatment duration. 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/1.73 m^2/year while on agalsidase alfa to -1.19 mL/min/1.73 m^2/year on PRX-102 in all patients. Male patients improved from -6.36 mL/min/1.73 m^2/year to -1.73 mL/min/1.73 m^2/year and female patients improved from -5.03 mL/min/1.73 m^2/year to -0.21 mL/min/1.73 m^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 who completed the study, ranging from ages 28 to 60 years, were as follows: mean eGFR 75.87 mL/min/1.73 m^2 in males, and 86.14 mL/min/1.73 m^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 who 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 which now sponsored by Chiesi.

Phase III BRIGHT Study

The *BRIGHT* study, which studied the 2 mg/kg every four weeks dosage, was completed in June 2020. This dosage was not approved by the EMA or the FDA.

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

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

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

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

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

Phase I/II Study

Sixteen adult, naïve Fabry patients (9 male and 7 female) completed our phase I/II clinical trial of PRX-102, 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 development cost reimbursements of $45.0 million, and is entitled to approximately $1.0 billion in potential milestone payments and tiered royalties of 15% - 35% (ex-US) and 15% - 40% (US). During the quarter ended June 30, 2023, we received net proceeds of $20.0 million representing a milestone payment earned upon the FDA’s approval of Elfabrio for adult Fabry patients.

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, capped at $7.5 million per year. Protalix Ltd. is also eligible to receive additional payments of up to a maximum of $760.0 million, in the aggregate, in regulatory and commercial milestone payments. Chiesi agreed to make tiered payments of 15% to 40% of 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 amending the Chiesi Agreements in order to provide our company with near-term capital. Chiesi agreed to make a $10.0 million payment to us before the end of the second quarter of 2021 in exchange for a $25.0 million reduction in a longer term regulatory milestone payment provided in the Chiesi EX-US Agreement. All other regulatory and commercial milestone payments remain unchanged. We received the payment in June 2021. We also agreed to negotiate certain manufacturing related matters.

On August 29, 2022, we entered into the F/F Agreement and the Letter Agreement with Chiesi. Under the F/F Agreement, we agreed to supply Chiesi with drug substance for PRX-102 and, following relevant technology and technical information transfer activities, Chiesi has agreed, among other things, to provide us with commercial fill/finish services for PRX-102, including to support the anticipated global launch of PRX-102. The F/F Agreement will expire December 31, 2025, unless terminated earlier in accordance with its terms and may be extended by mutual agreement in writing for an additional period of seven years. The Letter Agreement changed our obligations and those of 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 amended certain provisions of the License Agreements to reflect the appointment of Chiesi as a supplier to our company of commercial fill/finish services and the potential establishment of an initial alternate source of commercial fill/finish services.

As of March 1, 2023, sponsorship of the two extension studies was transferred to Chiesi, and Chiesi is now administering the extension studies.

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 Vpriv® and Sanofi's Cerdelga®, among others, was $1.6 billion in 2022, is forecasted to be approximately $1.6 billion in 2023 and is forecasted to grow at a CAGR of approximately 3.1% from 2022-2028.

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 the October 2015 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 (i.e., until October 2030).

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

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. 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 which supports the potential of PRX-115 to be a safe and effective treatment for severe gout. Results from the one-month multiple dosing toxicity studies in two species demonstrate that PRX-115 is well tolerated.

On March 21, 2023, the first patient was dosed in our phase I First in Human (FIH) clinical trial of PRX-115, a double-blind, placebo-controlled trial designed to evaluate the safety, pharmacokinetics, pharmacodynamics (reduction of uric acid) and immunogenicity of PRX-115 in patients with elevated uric acid levels (>6.0 mg/dL). The trial is a single ascending dose (SAD) study with up to seven cohorts, and patients are to be randomized 3:1 to receive a single intravenous (IV) dose of PRX-115 or a placebo. The study is being conducted at New Zealand Clinical Research (NZCR) under the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) and the Health and Disability Ethics Committee (HDEC) guidelines, and is expected to enroll approximately 56 patients with no previous exposure to PEGylated uricase. As of the date hereof, 16 patients have been dosed in this trial.

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 leads to substantial morbidity by causing severe pain, reduced quality of life, decreased physical function, increased healthcare costs, and lost economic productivity. Furthermore, gout is strongly associated with metabolic syndrome, and may contribute to myocardial infarction, type 2 diabetes mellitus, chronic kidney disease, or CKD, and premature mortality.

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% of the gout patient population is considered to have chronic refractory disease, and we believe the incidence of severe gout is 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 who 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 and 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 prolongs efficacy and increases tolerability in patients with refractory gout. Krystexxa is no longer marketed in the European Union. The EC withdrew the marketing authorization for Krystexxa in 2016 at the request of the marketing authorization holder which notified the EC of its decision not to market the product in the European Union for commercial reasons.

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 June 30, 2023, we hold a broad portfolio of over 80 patents in Europe, the United States, Israel and additional countries worldwide, as well as over 45 pending patent applications.

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, 2022.

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. As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to the assessment of sales reserves and valuation allowances. On an ongoing basis, we evaluate such estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Results of Operations

Three months ended June 30, 2023 compared to the three months ended June 30, 2022

Revenues from Selling Goods

We recorded revenues from selling goods of $15.1 million during the three months ended June 30, 2023, an increase of $11.7 million, or 344%, compared to revenues of $3.4 million for the three months ended June 30, 2022. The increase resulted primarily from an increase of $11.7 million in sales to Chiesi, following the approvals by the FDA and the EMA of Elfabrio.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $20.0 million for the three months ended June 30, 2023, an increase of $14.6 million, or 270%, compared to revenues of $5.4 million for the three months ended June 30, 2022. The increase resulted from the $20.0 million regulatory milestone payment from Chiesi in connection with the FDA approval of Elfabrio. 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 $6.1 million for the three months ended June 30, 2023 an increase of $2.0 million, or 49%, from cost of goods sold of $4.1 million for the three months ended June 30, 2022. The increase in cost of goods sold was primarily the result of the increase in sales of Elfabrio drug substance to Chiesi and royalties payable to the Israel Innovation Authority in connection with the Chiesi agreements.

Research and Development Expenses

For the three months ended June 30, 2023, our total research and development expenses were approximately $4.5 million comprised of approximately $1.7 million in subcontractor-related expenses, approximately $2.0 million of salary and related expenses, approximately $0.1 million of materials-related expenses and approximately $0.7 million of other expenses. For the three months ended June 30, 2022, our total research and development expenses were approximately $7.6 million comprised of approximately $4.4 million in subcontractor-related expenses, approximately $1.6 million of salary and related expenses, approximately $0.7 million of materials-related expenses and approximately $0.9 million of other expenses.

Total decrease in research and developments expenses was $3.1 million, or 41%, for the three months ended June 30, 2023 compared to the three months ended June 30, 2022. The decrease in research and development expenses primarily resulted from the completion of our Fabry clinical program and the regulatory processes related to the BLA and MAA review of Elfabrio by the applicable regulatory agencies.

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 $4.0 million for the three months ended June 30, 2023, an increase of $1.4 million, or 54%, compared to $2.6 million for the three months ended June 30, 2022. The increase resulted primarily from an increase of approximately $1.2 million in salary and related expenses due to one-time cash bonuses.

Financial Expenses, Net

Financial expenses, net were $0.8 million for the three months ended June 30, 2023, compared to financial income, net of $0.2 million for the three months ended June 30, 2022. The increase resulted primarily from an increase of $0.6 million in costs related to exchange rates as well as an increase in our convertible notes related expenses of $0.3 million net of a gain recognized due to conversions of a portion of the 2024 Notes of $0.4 million.

Income taxes

In the three months ended June 30, 2023, we recorded income taxes of approximately $0.3 million which were primarily the result of the provision for current taxes in respect of Section 174 of the TCJA. Section 174 eliminated the option to immediately deduct research and development expenses in the year incurred and requires us to capitalize and amortize these expenditures over 15 years (for out of U.S.-based research and development). In addition, during the three months ended June 30, 2023, we released a valuation allowance related to deferred tax assets of the U.S. jurisdiction that resulted in a net benefit to tax expense of $3.1 million.

Six months ended June 30, 2023 compared to the six months ended June 30, 2022

Revenues from Selling Goods

We recorded revenues from selling goods of $20.1 million during the six months ended June 30, 2023, an increase of $7.7 million, or 62%, compared to revenues of $12.4 million for the six months ended June 30, 2022. The increase resulted primarily from an increase of $11.5 million in sales to Chiesi, following the approvals by the FDA and the EMA of Elfabrio, which was partially offset by a decrease of $2.7 million in sales to Brazil and a decrease of $1.0 million in sales to Pfizer, both resulting from timing differences.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $24.5 million for the six months ended June 30, 2023, an increase of $12.1 million, or 98%, compared to revenues of $12.4 million for the six months ended June 30, 2022. The increase resulted from the $20.0 million regulatory milestone payment from Chiesi in connection with the FDA approval of Elfabrio which was partially offset by a decrease of $7.9 million in revenues recognized in connection with the Chiesi Agreements. 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 $9.2 million for the six months ended June 30, 2023, a decrease of $0.9 million, or 9%, from cost of goods sold of $10.1 million for the six months ended June 30, 2022. The decrease in cost of goods sold was primarily the result of a decrease

in sales of goods to Brazil and to Pfizer which was partially offset by an increase in sales of Elfabrio drug substance to Chiesi. Sales to Chiesi included certain drug substance costs which had already been recognized as research and development expenses as it was produced as part of research and development activities. Accordingly, the related cost of goods sold does not include the costs of such drug substance.

Research and Development Expenses

For the six months ended June 30, 2023, our total research and development expenses were approximately $10.3 million comprised of approximately $5.2 million in subcontractor-related expenses, approximately $3.6 million of salary and related expenses, approximately $0.3 million of materials-related expenses and approximately $1.2 million of other expenses. For the six months ended June 30, 2022, our total research and development expenses were approximately $16.3 million comprised of approximately $10.2 million in subcontractor-related expenses, approximately $3.7 million of salary and related expenses, approximately $0.9 million of materials-related expenses and approximately $1.5 million of other expenses.

Total decrease in research and developments expenses was $6.0 million, or 37%, for the six months ended June 30, 2023 compared to the six months ended June 30, 2022. The decrease in research and development expenses primarily resulted from the completion of our Fabry clinical program and of the regulatory processes related to the BLA and MAA review of Elfabrio by the applicable regulatory agencies.

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 $7.1 million for the six months ended June 30, 2023, an increase of $1.3 million, or 22%, compared to $5.8 million for the six months ended June 30, 2022. The increase resulted primarily from an increase of approximately $0.9 million in salary and related expenses due to one-time cash bonuses, an increase of $0.2 million in professional fees and of $0.2 million in travel, conferences and employee training expenses.

Financial Expenses, Net

Financial expenses, net were $1.3 million for the six months ended June 30, 2023, an increase of $1.1 million, or 550%, compared to $0.2 million for the six months ended June 30, 2022. The increase was primarily due to an increase of $0.7 million in costs related to exchange rates as well as an increase in our convertible notes related expenses of $0.3 million net of a gain recognized due to conversions of a portion of the 2024 Notes of $0.4 million.

Income taxes

In the six months ended June 30, 2023, we recorded income taxes of approximately $0.5 million which were primarily the result of the provision for current taxes in respect of Section 174 of the TCJA. Section 174 eliminated the option to immediately deduct research and development expenses in the year incurred and requires us to capitalize and amortize these expenditures over 15 years (for out of U.S.-based research and development). In addition, during the six months ended June 30, 2023, we released a valuation allowance related to deferred tax assets of the U.S. jurisdiction that resulted in a net benefit to tax expense of $3.1 million.

Liquidity and Capital Resources

Our sources of liquidity includes our cash and cash equivalents balance. At June 30, 2023, we had $48.2 million in cash and cash equivalents. We have primarily financed our operations through equity and debt financings, business collaborations, and grants funding.

During the year ended December 31, 2022, we raised gross proceeds equal to approximately $8.7 million from the sale of 7,473,038 shares of our common stock under our ATM program. During the six months ended June 30, 2023, we raised gross proceeds equal to approximately $24.9 million from sales of common stock under our ATM program through the sale of 12,560,150 shares of our common stock of which 4,347,668 shares were sold, and gross proceeds of approximately $10.0 million were raised, in the three months ended June 30, 2023.

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. As a result of the conversion of 2024 Notes during the six months ended June 30, 2023, the total principal amount of our remaining 2024 Notes outstanding decreased by approximately $8.3 million. As of June 30, 2023, the total principal amount of our 2024 Notes outstanding was $20.42 million.

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 June 30, 2023, we were in compliance with all covenants.

We believe that our cash and cash equivalents as of June 30, 2023 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 generated from operations was $2.0 million for the six months ended June 30, 2023. The net income for the six months ended June 30, 2023 of $16.2 million was decreased by an $13.2 million decrease in contracts liability, a $3.1 million increase in deferred tax assets and a $2.8 million increase in inventories. The net income was increased by a $3.6 million increase in accounts payable and accruals, $1.0 million in share-based compensation and $0.6 million in depreciation. Net cash provided by investing activities for the six months ended June 30, 2023 was $4.5 million and consisted primarily of proceeds from sale of short-term deposits. Net cash provided by financing activities was $24.7 million resulting primarily from the sale of common stock under our ATM program.

Net cash used in operations was $13.2 million for the six months ended June 30, 2022. The net loss for the six months ended June 30, 2022 of $7.6 million was increased by a $2.6 million decrease in contracts liability, a $4.9 million decrease in accounts payable and accruals and $1.0 million financial income, net (mainly exchange differences), and was partially offset by a $1.4 million decrease in inventories and a $1.1 million in share-based compensation. Net cash used in investing activities for the six months ended June 30, 2022 was $15.9 million and consisted primarily of investment in bank deposits. Net cash provided by financing activities was $2.6 million resulting mainly from the sale of common stock under our ATM program.

As a result of our significant research and development expenditures and the lack of significant revenue from sales of taliglucerase alfa, we have generated operating losses from our continuing operations since our inception. Our outstanding 2024 Notes are secured by a perfected lien on all of our assets. 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 June 30, 2023, we were in compliance with all covenants.

During the six months ended June 30, 2023, we issued, in the aggregate, 538,822 shares of our common stock in connection with cash and cashless exercises of our outstanding warrants to purchase shares of our common stock at an exercise price equal to $2.36 per share which were initially issued on March 18, 2020 as part of our private placement of common stock and warrants, or the 2020 Warrants. In connection with the exercises, we generated net proceeds equal to $0.7 million and retired 2020 Warrants to purchase 1,146,810 shares of common stock. As of June 30, 2023, 2020 Warrants to purchase 13,439,712 shares were outstanding.

In addition, during the six months ended June 30, 2023, we issued, in the aggregate, 4,691,623 shares of our common stock in connection with a number of conversions of 2024 Notes. In connection with such conversions, during the six months ended June 30, 2023, we paid to the converting holders $0.9 million representing cash payments due to accrued but unpaid interest, make-whole interest payments and payments in lieu of fractional shares. As a result of the conversion of 2024 Notes during the six months ended

June 30, 2023, the total principal amount of our remaining 2024 Notes outstanding decreased by approximately $8.3 million. As of June 30, 2023, the total principal amount of our 2024 Notes outstanding was $20.42 million.

Future Funding Requirements

We expect to continue to incur expenditures in the near future as we increase our research and developments efforts with respect to our product candidates. We cannot anticipate the costs or the timing of the occurrence of such costs. We also expect to increase the revenues generated from the sales of our approved drug products. To the extent we need to obtain additional financing in excess of such anticipated revenues, 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, (v) payments of principal and interest on our outstanding 2024 Notes and (vi) tax payments. We believe that the funds currently available to us are sufficient to satisfy our capital needs for at least 12 months.

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

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

We expect to finance our future cash needs through sales of our approved drug products (Elelyso and Elfabrio), 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 milestone payments and royalties that may become payable under the Chiesi Agreements. As of June 30, 2023, shares of our common stock for total gross proceeds of approximately $6.4 million remain available to be sold under our 2023 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. We do not believe currency fluctuations have had a material effect on our results of operations during the three and six months ended June 30, 2023.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of June 30, 2023 and December 31, 2022.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Currency Exchange Risk

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

Approximately 43% of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A revaluation of 1% of the NIS will affect our loss before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Three Months Ended June 30,		Six Months Ended June 30,		December 31,
	2023	2022	2023	2022	2022
Average rate for period	3.648	3.346	3.592	3.272	3.360
Rate at period-end	3.700	3.500	3.700	3.500	3.519

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Inherent Limitations on Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended June 30, 2023 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, 2022.

Any current products or future product candidates may cause serious adverse events, or SAEs, undesirable side effects or have other properties that could halt their clinical development, prevent, delay, or cause the withdrawal of their regulatory approval, limit their commercial potential, or result in material negative consequences.

As with most infused products, use of our products or any current or future product candidates could be associated with undesirable side effects or adverse events which can vary in severity and frequency. From time to time, we have observed serious adverse events in clinical studies of our products and product candidates. For example, while conducting clinical trials we have observed treatable anaphylactic reactions. In addition, as indicated in the boxed warning with which Elfabrio was approved by the FDA, patients treated with Elfabrio have experienced hypersensitivity reactions, including anaphylaxis. There are postmarketing requirements under the U.S. Federal Food, Drug, and Cosmetic Act included with the approval of Elfabrio by the FDA. For example, the FDA requires that a worldwide descriptive study be conducted that collects prospective and retrospective data in women and their offspring exposed to Elfabrio during pregnancy and/or lactation to assess risk of pregnancy and material complications, adverse effects on the developing fetus and neonate, and adverse effects on the infant. Furthermore, the approval of pharmaceutical products generally includes requirements related to the preparation of a Risk Evaluation and Mitigation Strategy, or REMS, or a risk management plan as required by the EMA, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use. For example, Chiesi must follow a risk management plan agreed upon with the EMA with respect to Elfabrio, which includes risk minimization measures in connection with risks associated with hypersensitivity reactions and possible medication errors in the home infusion setting. Our product candidates, if approved, may also be subject to certain post-authorization reporting requirements. As an example, the EMA has required that Chiesi submit pharmacovigilance documents intended to provide post-authorization evaluation of Elfabrio's risk-benefit balance at defined time points after authorization, beginning within six months of authorization, and that we agree with the National Competent Authority on an educational program about home administration prior to use of Elfabrio in the home setting. Any of the foregoing, including the boxed warning, could prevent us or our collaborators from achieving or maintaining market acceptance of a product or a particular product candidate and could materially harm our business, results of operations, and prospects, and could adversely impact our financial condition, results of operations, ability to raise additional financing or the market price of our common stock.

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	Fifth Amendment to Certificate of Incorporation of the Company					X
3.7	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	February 27, 2023	
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†	Amended and Restated Pro BioTherapeutics, Inc. 2006 Stock Incentive Plan, as amended					
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.

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: August 7, 2023

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

Date: August 7, 2023

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

Exhibit 3.6

FIFTH CERTIFICATE OF AMENDMENT TO
CERTIFICATE OF INCORPORATION OF
PROTALIX BIOTHERAPEUTICS, INC.

(Pursuant to Section 242 of the
General Corporation Law of the State of Delaware)

Protalix BioTherapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware, hereby certifies as follows:

1. The name of the corporation is Protalix BioTherapeutics, Inc. (the "Corporation"). The Certificate of Incorporation of the Corporation was filed with the Secretary of the State of Delaware on March 30, 2016, as amended by that Certificate of Amendment dated August 16, 2016, that Second Certificate of Amendment dated January 15, 2019, that Third Certificate of Amendment dated December 16, 2019 and that Fourth Certificate of Amendment dated August 2, 2022 (the "Certificate of Incorporation").

2. This Certificate of Amendment to Certificate of Incorporation of the Corporation was duly adopted by the Board of Directors of the Corporation pursuant to a resolution setting forth the proposed amendment of the Certificate of Incorporation and declaring said amendment to be advisable.

3. Article III of the Certificate of Incorporation, as amended, is hereby amended and restated in its entirety as follows:

> "The Corporation is authorized to issue the following shares of capital stock: (a) 185,000,000 shares of common stock, par value $.001 per share (the "Common Stock"); and (b) 100,000,000 shares of preferred stock, par value $.0001 per share (the "Preferred Stock"). The voting rights, the rights of redemption and other relative rights and preferences of the Preferred Stock shall be established by the Board of Directors.
>
> The Board of Directors may authorize the issuance of such stock to such persons upon such terms and for such consideration in cash, property or services as the Board of Directors may determine and as may be allowed by law. The just valuation of such property or services shall be fixed by the Board of Directors. All such stock when issued shall be fully paid and exempt from assessment."

4. The aforesaid amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

[Remainder of this page intentionally left blank.]

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to Certificate of Incorporation to be signed by its duly authorized President and Chief Executive Officer this 25th day of July, 2023.

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 10.1

PROTALIX BIOTHERAPEUTICS, INC.
AMENDED AND RESTATED 2006 STOCK INCENTIVE PLAN, AS AMENDED
(June 28, 2023)

1. Purposes of the Plan. The purposes of this Plan are to attract and retain the best available personnel, to provide additional incentives to Employees, Directors and Consultants and to promote the success of the Company's business.

2. Definitions. The following definitions shall apply as used herein and in the individual Award Agreements except as defined otherwise in an individual Award Agreement. In the event a term is separately defined in an individual Award Agreement, such definition shall supercede the definition contained in this Section 2.

(a) "3(I) Option" means Award granted under Section 3(I).

(b) "102 Option" means Award granted under Section 102.

(c) "Administrator" means the Board or any of the Committees appointed to administer the Plan.

(d) "Affiliate" and "Associate" shall have the respective meanings ascribed to such terms in Rule 12b-2 promulgated under the Exchange Act.

(e) "Applicable Laws" means the legal requirements relating to the Plan and the Awards under applicable provisions of federal securities laws, state corporate and securities laws, the Code, the rules of any applicable stock exchange or national market system, and the rules of any non-U.S. jurisdiction applicable to Awards granted to residents therein.

(f) "Assumed" means that pursuant to a Corporate Transaction either (i) the Award is expressly affirmed by the Company or (ii) the contractual obligations represented by the Award are expressly assumed (and not simply by operation of law) by the successor entity or its Parent in connection with the Corporate Transaction with appropriate adjustments to the number and type of securities of the successor entity or its Parent subject to the Award and the exercise or purchase price thereof which at least preserves the compensation element of the Award existing at the time of the Corporate Transaction as determined in accordance with the instruments evidencing the agreement to assume the Award.

(g) "Award" means the grant of an Option, SAR, Dividend Equivalent Right, Restricted Stock, Restricted Stock Unit or other right or benefit under the Plan.

(h) "Award Agreement" means the written agreement evidencing the grant of an Award executed by the Company and the Grantee, including any amendments thereto.

(i) "Board" means the Board of Directors of the Company.

(j) "Cause" means, with respect to the termination by the Company or a Related Entity of the Grantee's Continuous Service, that such termination is for "Cause" as such term (or word of like import) is expressly defined in a then-effective written agreement between the Grantee and the Company or such Related Entity, or in the absence of such then-effective written agreement and definition, is based on, in the determination of the Administrator, the Grantee's: (i) performance of any act or failure to perform any act in bad faith which is materially detrimental to the Company or a Related Entity as reasonably determined in good faith by a unanimous decision of members of the Board entitled to vote thereon; (ii) dishonesty, intentional misconduct or material breach of any agreement with the Company or a Related Entity; (iii) commission of a crime involving dishonesty, breach of trust, or physical or emotional harm to any person; (iv) embezzlement of funds of the Company or a Related Entity; (v) ownership, direct or indirect (i.e., by means of a holding company or family member), of an interest in a person or entity (other than a minority interest in a publicly traded company) in competition with the products or services of the Company or a Related Entity, including those products or services contemplated in a plan adopted by the Board; (vi) any breach of the Grantee's fiduciary duties or duties of care to the Company or a Related Entity (except for conduct taken in good faith); (vii) any material failure to carry out a reasonable and legitimate directive of the Board; or (viii) any material breach of an Employee's undertakings of confidentiality and non competition.

(k) "Change in Control" means a change in ownership or control of the Company effected through either of the following transactions:

(i) the direct or indirect acquisition by any person or related group of persons (other than an acquisition from or by the Company or by a Company-sponsored employee benefit plan or by a person that directly or indirectly controls, is controlled by, or is under common control with, the Company) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities pursuant to a tender or exchange offer made directly to the Company's stockholders which a majority of the Continuing Directors who are not Affiliates or Associates of the offeror do not recommend such stockholders accept, or

(ii) a change in the composition of the Board over a period of twelve (12) months or less such that a majority of the Board members (rounded up to the next whole number) ceases, by reason of one or more contested elections for Board membership, to be comprised of individuals who are Continuing Directors.

(l) "Code" means the Internal Revenue Code of 1986, as amended.

(m) "Committee" means any committee composed of members of the Board appointed by the Board to administer the Plan.

(n) "Common Stock" means the common stock of the Company.

(o) "Company" means Protalix BioTherapeutics, Inc., a Delaware corporation, or any successor entity that adopts the Plan in connection with a Corporate Transaction.

(p) "Consultant" means any person (other than an Employee or a Director, solely with respect to rendering services in such person's capacity as a Director) who is engaged by the Company or any Related Entity to render consulting or advisory services to the Company or such Related Entity.

(q) "Continuing Directors" means members of the Board who either (i) have been Board members continuously for a period of at least twelve (12) months or (ii) have been Board members for less than twelve (12) months and were elected or nominated for election as Board members by at least a majority of the Board members described in clause (i) who were still in office at the time such election or nomination was approved by the Board.

(r) "Continuous Service" means that the provision of services to the Company or a Related Entity in any capacity of Employee, Director or Consultant is not interrupted or terminated. In jurisdictions requiring notice in advance of an effective termination as an Employee, Director or Consultant, Continuous Service shall be deemed terminated upon the actual cessation of providing services to the Company or a Related Entity notwithstanding any required notice period that must be fulfilled before a termination as an Employee, Director or Consultant can be effective under Applicable Laws. A Grantee's Continuous Service shall be deemed to have terminated either upon an actual termination of Continuous Service or upon the entity for which the Grantee provides services ceasing to be a Related Entity. Continuous Service shall not be considered interrupted in the case of (i) any approved leave of absence, (ii) transfers among the Company, any Related Entity, or any successor, in any capacity of Employee, Director or Consultant, or (iii) any change in status as long as the individual remains in the service of the Company or a Related Entity in any capacity of Employee, Director or Consultant (except as otherwise provided in the Award Agreement). An approved leave of absence shall include sick leave, military leave, or any other authorized personal leave. For purposes of each Incentive Stock Option granted under the Plan, if such leave exceeds three (3) months, and reemployment upon expiration of such leave is not guaranteed by statute or contract, then the Incentive Stock Option shall be treated as a Non-Qualified Stock Option on the day three (3) months and one (1) day following the expiration of such three (3) month period.

(s) "Corporate Transaction" means any of the following transactions, provided, however, that the Administrator shall determine under parts (iv) and (v) whether multiple transactions are related, and its determination shall be final, binding and conclusive:

(i) a merger or consolidation in which the Company is not the surviving entity, except for a transaction the principal purpose of which is to change the state in which the Company is incorporated;

(ii) the sale, transfer or other disposition of all or substantially all of the assets of the Company;

(iii) the complete liquidation or dissolution of the Company;

(iv) any reverse merger or series of related transactions culminating in a reverse merger (including, but not limited to, a tender offer followed by a reverse merger) in which the Company is the surviving entity but (A) the shares of Common Stock outstanding immediately prior to such merger are converted or exchanged by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (B) in which securities possessing more than forty percent (40%) of the total combined voting power of the Company's outstanding securities are transferred to a person or persons different from those who held such securities immediately prior to such merger or the initial transaction culminating in such merger; or

(v) acquisition in a single or series of related transactions by any person or related group of persons (other than the Company or by a Company-sponsored employee benefit plan) of beneficial ownership (within the meaning of Rule 13d-3 of the Exchange Act) of securities possessing more than fifty percent (50%) of the total combined voting power of the Company's outstanding securities but excluding any such transaction or series of related transactions that the Administrator determines shall not be a Corporate Transaction (provided however that the Administrator shall have no discretion in connection with a Corporate Transaction for the purchase of all or substantially all of the shares of the Company unless the principal purpose of such transaction is to change the state in which the Company is incorporated).

(t) "Covered Employee" means an Employee who is a "covered employee" under Section 162(m)(3) of the Code.

(u) "Director" means a member of the Board or the board of directors of any Related Entity.

(v) "Disability" means as defined under the long-term disability policy of the Company or the Related Entity to which the Grantee provides services regardless of whether the Grantee is covered by such policy. If the Company or the Related Entity to which the Grantee provides service does not have a long-term disability plan in place, "Disability" means that a Grantee is unable to carry out the responsibilities and functions of the position held by the Grantee by reason of any medically determinable physical or mental impairment for a period of not less than ninety (90) consecutive days. A Grantee will not be considered to have incurred a Disability unless he or she furnishes proof of such impairment sufficient to satisfy the Administrator in its discretion.

(w) "Dividend Equivalent Right" means a right entitling the Grantee to compensation measured by dividends paid with respect to Common Stock.

(x) "Employee" means any person, including an Officer or Director, who is in the employ of the Company or any Related Entity, subject to the control and direction of the Company or any Related Entity as to both the work to be performed and the manner and method of performance. The payment of a director's fee by the Company or a Related Entity shall not be sufficient to constitute "employment" by the Company.

(y) "Exchange Act" means the Securities Exchange Act of 1934, as amended.

(z) "Fair Market Value" means, as of any date, the value of Common Stock determined as follows:

(i) If the Common Stock is listed on one or more established stock exchanges or national market systems, including without limitation the American Stock Exchange, its Fair Market Value shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on the principal exchange or system on which the Common Stock is listed (as determined by the Administrator) on the date of determination (or, if no closing sales price or closing bid was reported on that date, as applicable, on the last trading date such closing sales price or closing bid was reported), as reported in The Wall Street Journal or such other source as the Administrator deems reliable;

(ii) If the Common Stock is regularly quoted on an automated quotation system (including the OTC Bulletin Board) or by a recognized securities dealer, its Fair Market Value shall be the closing sales price for such stock as quoted on such system or by such securities dealer on the date of determination, but if selling prices are not reported, the Fair Market Value of a share of Common Stock shall be the mean between the high bid and low asked prices for the Common Stock on the date of determination (or, if no such prices were reported on that date, on the last date such prices were reported), as reported in The Wall Street Journal or such other source as the Administrator deems reliable; or

(iii) In the absence of an established market for the Common Stock of the type described in (i) and (ii), above, the Fair Market Value thereof shall be determined by the Administrator in good faith.

(aa) "Grantee" means an Employee, Director or Consultant who receives an Award under the Plan.

(bb) "Incentive Stock Option" means an Option intended to qualify as an incentive stock option within the meaning of Section 422 of the Code.

(cc) "Israeli Employee" means Employees, office holders of the Company or a Related Company ("Nosei Misra" - as such term is defined in the Israeli Companies Law 1999) and Directors (excluding those who are considered a "Controlling Shareholder" pursuant to Section 32(9) of the Tax Ordinance or otherwise excluded by the Tax Ordinance).

(dd) "Israeli Grantee" means Grantees who are residents of the State of Israel or those who are deemed to be residents of the State of Israel for the payment of tax (whether such grantee is entitled to the tax benefits under Section 102 or not).

(ee) "ITA" means Israeli Tax Authorities.

(ff) "Non-Employee" means Consultants or any other person who is not an Israeli Employee.

(gg) "Non-Qualified Stock Option" means an Option not intended to qualify as an Incentive Stock Option.

(hh) "Non-Trustee 102 Option" shall mean a 102 Option granted pursuant to Section 102(c) of the Tax Ordinance and not held in trust by the Trustee.

(ii) "Officer" means a person who is an officer of the Company or a Related Entity within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(jj) "Option" means an option to purchase Shares pursuant to an Award Agreement granted under the Plan.

(kk) "Parent" means a "parent corporation", whether now or hereafter existing, as defined in Section 424(e) of the Code.

(ll) "Performance-Based Compensation" means compensation qualifying as "performance-based compensation" under Section 162(m) of the Code.

(mm) "Plan" means this Amended and Restated 2006 Stock Incentive Plan.

(nn) "Related Entity" means any Parent or Subsidiary of the Company. With respect to Israeli Grantees of 102 Options, the definition shall further include any entity permitted under Section 102 (a) of the Tax Ordinance.

(oo) "Replaced" means that pursuant to a Corporate Transaction the Award is replaced with a comparable stock award or a cash incentive program of the Company, the successor entity (if applicable) or Parent of either of them which preserves the compensation element of such Award existing at the time of the Corporate Transaction and provides for subsequent payout in accordance with the same (or a more favorable) vesting schedule applicable to such Award. The determination of Award comparability shall be made by the Administrator and its determination shall be final, binding and conclusive.

(pp) "Restricted Stock" means Shares issued under the Plan to the Grantee for such consideration, if any, and subject to such restrictions on transfer, rights of first refusal, repurchase provisions, forfeiture provisions, and other terms and conditions as established by the Administrator.

(qq) "Restricted Stock Units" means an Award which may be earned in whole or in part upon the passage of time or the attainment of performance criteria established by the Administrator and which may be settled for cash, Shares or other securities or a combination of cash, Shares or other securities as established by the Administrator.

(rr) "Rule 16b-3" means Rule 16b-3 promulgated under the Exchange Act or any successor thereto.

(ss) "SAR" means a stock appreciation right entitling the Grantee to Shares or cash compensation, as established by the Administrator, measured by appreciation in the value of Common Stock.

(tt) "Section 3(I)" means section 3(I) of the Tax Ordinance as may be amended from time to time.

(uu) "Section 102" means section 102 of the Tax Ordinance as may be amended from time to time.

(vv) "Share" means a share of the Common Stock.

(ww) "Subsidiary" means a "subsidiary corporation", whether now or hereafter existing, as defined in Section 424(f) of the Code.

(xx) "Tax Ordinance" means the Israeli Income Tax Ordinance [New Version], 1961 (including as amended pursuant to Amendment 132 thereto) and to the extent not specifically indicated hereunder also the rules, regulations and orders or procedures promulgated thereunder from time to time, as amended or replaced from time to time.

(yy) "Trustee" means any individual appointed by the Company to serve as trustee and approved by the ITA, in accordance with the provisions of Section 102(a) of the Tax Ordinance and the regulations promulgated thereunder.

(zz) "Trustee 102 Option" means a 102 Option granted pursuant to Section 102(b) of the Tax Ordinance and held in trust by the Trustee for the benefit of an Israeli Grantee.

3. Stock Subject to the Plan.

(a) Subject to the provisions of Section 10, below, the maximum aggregate number of Shares which may be issued pursuant to all Awards (including Incentive Stock Options) under the Plan is 12,475,171 Shares. Notwithstanding the foregoing, any Shares issued from and after November 10, 2014 in connection with Awards other than Options and SARs shall be counted against the limit set forth herein as one and one-half (1.5) Shares for every one (1) Share issued in connection with such Award (and shall be counted as one and one-half (1.5) Shares for every one (1) Share returned or deemed not have been issued from the Plan pursuant to Section 3(b) below in connection with Awards other than Options and SARs). The Shares to be issued pursuant to Awards may be authorized, but unissued, or reacquired Common Stock.

(b) Any Shares covered by an Award (or portion of an Award) which is forfeited, canceled or expires (whether voluntarily or involuntarily) shall be deemed not to have been issued for purposes of determining the maximum aggregate number of Shares which may be issued under the Plan. Shares that actually have been issued under the Plan pursuant to an Award shall not be returned to the Plan and shall not become available for future issuance under the Plan, except that if unvested Shares are forfeited, or repurchased by the Company at the lower of their original purchase price or their Fair Market Value at the time of repurchase, such Shares shall become available for future grant under the Plan. Notwithstanding anything to the contrary contained herein: (i) Shares tendered or withheld in payment of an Option exercise price shall not be returned to the Plan and shall not become available for future issuance under the Plan; (ii) Shares withheld by the Company to satisfy any tax withholding obligation shall not be returned to the Plan and shall not become available for future issuance under the Plan; and (iii) all Shares covered by the portion of an SAR that is exercised (whether or not Shares are actually issued to the Grantee upon exercise of the SAR) shall be considered issued pursuant to the Plan.

4. Administration of the Plan.

(a) Plan Administrator.

(i) Administration with Respect to Directors and Officers. With respect to grants of Awards to Directors or Employees who are also Officers or Directors of the Company, the Plan shall be administered by (A) the Board or (B) a Committee designated by the Board, which Committee shall be constituted in such a manner as to satisfy the Applicable Laws and to permit such grants and related transactions under the Plan to be exempt from

Section 16(b) of the Exchange Act in accordance with Rule 16b-3. Once appointed, such Committee shall continue to serve in its designated capacity until otherwise directed by the Board.

(ii) Administration With Respect to Consultants and Other Employees. With respect to grants of Awards to Employees or Consultants who are neither Directors nor Officers of the Company, the Plan shall be administered by (A) the Board or (B) a Committee designated by the Board, which Committee shall be constituted in such a manner as to satisfy the Applicable Laws. Once appointed, such Committee shall continue to serve in its designated capacity until otherwise directed by the Board. The Board may authorize one or more Officers to grant such Awards and may limit such authority as the Board determines from time to time.

(iii) Administration With Respect to Covered Employees. Notwithstanding the foregoing, grants of Awards to any Covered Employee intended to qualify as Performance-Based Compensation shall be made only by a Committee (or subcommittee of a Committee) which is comprised solely of two or more Directors eligible to serve on a committee making Awards qualifying as Performance-Based Compensation. In the case of such Awards granted to Covered Employees, references to the "Administrator" or to a "Committee" shall be deemed to be references to such Committee or subcommittee.

(iv) Administration With Respect to Israeli Grantees. With respect to grants of Awards to Israeli Grantees, the Plan shall be administered by (A) the Board or (B) a Committee or one or more Officers designated by the Board, which Committee or Officers shall be constituted or appointed in such a manner as to satisfy the ITA and the Applicable Laws applicable to Awards for Israeli Grantees. Once appointed, such Committee or Officer shall continue to serve in its/his/her designated capacity until otherwise directed by the Board.

(v) Administration Errors. In the event an Award is granted in a manner inconsistent with the provisions of this subsection (a), such Award shall be presumptively valid as of its grant date to the extent permitted by the Applicable Laws.

(b) Powers of the Administrator. Subject to Applicable Laws and the provisions of the Plan (including any other powers given to the Administrator hereunder), and except as otherwise provided by the Board, the Administrator shall have the authority, in its discretion:

(i) to select the Employees, Directors and Consultants to whom Awards may be granted from time to time hereunder;

(ii) to determine whether and to what extent Awards are granted hereunder;

(iii) to determine the number of Shares or the amount of other consideration to be covered by each Award granted hereunder;

(iv) to approve forms of Award Agreements for use under the Plan;

(v) to determine the terms and conditions of any Award granted hereunder;

(vi) to amend the terms of any outstanding Award granted under the Plan, provided that (A) any amendment that would adversely affect the Grantee's rights under an outstanding Award shall not be made without the Grantee's written consent, provided, however, that an amendment or modification that may cause an Incentive Stock Option to become a Non-Qualified Stock Option shall not be treated as adversely affecting the rights of the Grantee, (B) the reduction of the exercise price of any Option awarded under the Plan and the base appreciation amount of any SAR awarded under the Plan shall be subject to stockholder approval and (C) canceling an Option or SAR at a time when its exercise price or base appreciation amount (as applicable) exceeds the Fair Market Value of the underlying Shares, in exchange for another Option, SAR, Restricted Stock, or other Award or for cash shall be subject to stockholder approval, unless the cancellation and exchange occurs in connection with a Corporate Transaction. Notwithstanding the foregoing, canceling an Option or SAR in exchange for another Option, SAR, Restricted Stock, or other Award or for cash with an exercise price, purchase price or base appreciation amount (as applicable) that is equal to or greater than the exercise price or base appreciation amount (as applicable) of the original Option or SAR shall not be subject to stockholder approval;

(vii) to construe and interpret the terms of the Plan and Awards, including without limitation, any notice of award or Award Agreement, granted pursuant to the Plan;

(viii) to grant Awards to Employees, Directors and Consultants employed outside the United States on such terms and conditions different from those specified in the Plan as may, in the judgment of the Administrator, be necessary or desirable to further the purpose of the Plan; and

(ix) to designate Awards as 102 Options (whether through a trustee or not) or 3(I) Options subject to the limitations under the ITA or any other Applicable Law and to determine the type and route of the Trustee 102 Options.

(x) to take such other action, not inconsistent with the terms of the Plan, as the Administrator deems appropriate.

The express grant in the Plan of any specific power to the Administrator shall not be construed as limiting any power or authority of the Administrator; provided that the Administrator may not exercise any right or power reserved to the Board. Any decision made, or action taken, by the Administrator or in connection with the administration of this Plan shall be final, conclusive and binding on all persons having an interest in the Plan.

(c) Indemnification. In addition to such other rights of indemnification as they may have as members of the Board or as Officers or Employees of the Company or a Related Entity, members of the Board and any Officers or Employees of the Company or a Related Entity to whom authority to act for the Board, the Administrator or the Company is delegated shall be defended and indemnified by the Company to the extent permitted by law on an after-tax basis against all reasonable expenses, including attorneys' fees, actually and necessarily incurred in connection with the defense of any claim, investigation, action, suit or proceeding, or in connection with any appeal therein, to which they or any of them may be a party by reason of any action taken or failure to act under or in connection with the Plan, or any Award granted hereunder, and against all amounts paid by them in settlement thereof (provided such settlement is approved by the Company) or paid by them in satisfaction of a judgment in any such claim, investigation, action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such claim, investigation, action, suit or proceeding that such person is liable for gross negligence, bad faith or intentional misconduct; provided, however, that within thirty (30) days after the institution of such claim, investigation, action, suit or proceeding, such person shall offer to the Company, in writing, the opportunity at the Company's expense to defend the same.

5. Eligibility. Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants. Incentive Stock Options may be granted only to Employees of the Company or a Parent or a Subsidiary of the Company. An Employee, Director or Consultant who has been granted an Award may, if otherwise eligible, be granted additional Awards. Awards may be granted to such Employees, Directors or Consultants who are residing in non-U.S. jurisdictions as the Administrator may determine from time to time, provided however that Awards to Israeli Grantees under Section 102 or Section 3(I) of the Tax Ordinance shall be subject to Section 20 below.

The Company does not warrant that the Plan will be recognized by the income tax authorities in any jurisdiction or that future changes will not be made to the provisions of applicable laws or rules or regulations which are promulgated from time to time thereunder, or that any exemption or benefit currently available, whether by the ITA pursuant to Section 102 or otherwise, will not be abolished.

6. Terms and Conditions of Awards.

(a) Types of Awards. The Administrator is authorized under the Plan to award any type of arrangement to an Employee, Director or Consultant that is not inconsistent with the provisions of the Plan and that by its terms involves or might involve the issuance of (i) Shares, (ii) cash or (iii) an Option, a SAR, or similar right with a fixed or variable price related to the Fair Market Value of the Shares and with an exercise or conversion privilege related to the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions. Such awards include, without limitation, Options, SARs, sales or bonuses of Restricted Stock, Restricted Stock Units or Dividend Equivalent Rights, and an Award may consist of one such security or benefit, or two (2) or more of them in any combination or alternative.

(b) Designation of Award. Each Award shall be designated in the Award Agreement. In the case of an Option, the Option shall be designated as either an Incentive Stock Option or a Non-Qualified Stock Option and with respect to Israeli Grantees may be further designated as 102 Options or 3(I) Options under the Tax Ordinance subject to the qualifications described in Section 20 below. However, notwithstanding such designation, an Option will qualify as an Incentive Stock Option under the Code only to the extent the $100,000 dollar limitation of Section 422(d) of the Code is not exceeded. The $100,000 limitation of Section 422(d) of the Code is calculated based on the aggregate Fair Market Value of the Shares subject to Options designated as Incentive Stock Options which become exercisable for

the first time by a Grantee during any calendar year (under all plans of the Company or any Parent or Subsidiary of the Company). For purposes of this calculation, Incentive Stock Options shall be taken into account in the order in which they were granted, and the Fair Market Value of the Shares shall be determined as of the grant date of the relevant Option. In the event that the Code or the regulations promulgated thereunder are amended after the date the Plan becomes effective to provide for a different limit on the Fair Market Value of Shares permitted to be subject to Incentive Stock Options, then such different limit will be automatically incorporated herein and will apply to any Options granted after the effective date of such amendment.

(c) Conditions of Award. Subject to the terms of the Plan, the Administrator shall determine the provisions, terms, and conditions of each Award including, but not limited to, the Award vesting schedule, repurchase provisions, rights of first refusal, forfeiture provisions, form of payment (cash, Shares, or other consideration) upon settlement of the Award, payment contingencies, and satisfaction of any performance criteria. The performance criteria established by the Administrator may be based on any one of, or combination of, the following: (i) increase in share price, (ii) earnings per share, (iii) total stockholder return, (iv) operating margin, (v) gross margin, (vi) return on equity, (vii) return on assets, (viii) return on investment, (ix) operating income, (x) net operating income, (xi) pre-tax profit, (xii) cash flow, (xiii) revenue, (xiv) expenses, (xv) earnings before interest, taxes and depreciation, (xvi) economic value added and (xvii) market share. The performance criteria may be applicable to the Company, Related Entities and/or any individual business units of the Company or any Related Entity. Partial achievement of the specified criteria may result in a payment or vesting corresponding to the degree of achievement as specified in the Award Agreement. In addition, the performance criteria shall be calculated in accordance with generally accepted accounting principles, but excluding the effect (whether positive or negative) of any change in accounting standards and any extraordinary, unusual or nonrecurring item, as determined by the Administrator, occurring after the establishment of the performance criteria applicable to the Award intended to be performance-based compensation. Each such adjustment, if any, shall be made solely for the purpose of providing a consistent basis from period to period for the calculation of performance criteria in order to prevent the dilution or enlargement of the Grantee's rights with respect to an Award intended to be performance-based compensation.

(d) Acquisitions and Other Transactions. The Administrator may issue Awards under the Plan in settlement, assumption or substitution for, outstanding awards or obligations to grant future awards in connection with the Company or a Related Entity acquiring another entity, an interest in another entity or an additional interest in a Related Entity whether by merger, stock purchase, asset purchase or other form of transaction.

(e) Deferral of Award Payment. The Administrator may establish one or more programs under the Plan to permit selected Grantees the opportunity to elect to defer receipt of consideration upon exercise of an Award, satisfaction of performance criteria, or other event that absent the election would entitle the Grantee to payment or receipt of Shares or other consideration under an Award. The Administrator may establish the election procedures, the timing of such elections, the mechanisms for payments of, and accrual of interest or other earnings, if any, on amounts, Shares or other consideration so deferred, and such other terms, conditions, rules and procedures that the Administrator deems advisable for the administration of any such deferral program.

(f) Separate Programs. The Administrator may establish one or more separate programs under the Plan for the purpose of issuing particular forms of Awards to one or more classes of Grantees on such terms and conditions as determined by the Administrator from time to time.

(g) Individual Limitations on Awards.

(i) Individual Limit for Options and SARs. The maximum number of Shares with respect to which Options and SARs may be granted to any Grantee in any calendar year shall be 12,475,171 Shares. Shares which shall not count against the limit set forth in the previous sentence. The foregoing limitations shall be adjusted proportionately in connection with any change in the Company's capitalization pursuant to Section 10, below. To the extent required by Section 162(m) of the Code or the regulations thereunder, in applying the foregoing limitations with respect to a Grantee, if any Option or SAR is canceled, the canceled Option or SAR shall continue to count against the maximum number of Shares with respect to which Options and SARs may be granted to the Grantee. For this purpose, the repricing of an Option (or in the case of a SAR, the base amount on which the stock appreciation is calculated is reduced to reflect a reduction in the Fair Market Value of the Common Stock) shall be treated as the cancellation of the existing Option or SAR and the grant of a new Option or SAR.

(ii) Individual Limit for Restricted Stock and Restricted Stock Units. For awards of Restricted Stock and Restricted Stock Units that are intended to be Performance-Based Compensation, the maximum

number of Shares with respect to which such Awards may be granted to any Grantee in any calendar year shall be 12,475,171 Shares. The foregoing limitation shall be adjusted proportionately in connection with any change in the Company's capitalization pursuant to Section 10, below.

(iii) Deferral. If the vesting or receipt of Shares under an Award is deferred to a later date, any amount (whether denominated in Shares or cash) paid in addition to the original number of Shares subject to such Award will not be treated as an increase in the number of Shares subject to the Award if the additional amount is based either on a reasonable rate of interest or on one or more predetermined actual investments such that the amount payable by the Company at the later date will be based on the actual rate of return of a specific investment (including any decrease as well as any increase in the value of an investment).

(h) Early Exercise. The Award Agreement may, but need not, include a provision whereby the Grantee may elect at any time while an Employee, Director or Consultant to exercise any part or all of the Award prior to full vesting of the Award. Any unvested Shares received pursuant to such exercise may be subject to a repurchase right in favor of the Company or a Related Entity or to any other restriction the Administrator determines to be appropriate.

(i) Term of Award. The term of each Award shall be the term stated in the Award Agreement, provided, however, that the term of an Award shall be no more than ten (10) years from the date of grant thereof. However, in the case of an Incentive Stock Option granted to a Grantee who, at the time the Option is granted, owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Parent or Subsidiary of the Company, the term of the Incentive Stock Option shall be five (5) years from the date of grant thereof or such shorter term as may be provided in the Award Agreement.

(j) Transferability of Awards. Incentive Stock Options or Options to Israeli Grantees may not be sold, pledged, assigned, hypothecated, transferred, or disposed of in any manner other than by will or by the laws of descent or distribution and may be exercised, during the lifetime of the Grantee, only by the Grantee. Other Awards shall be transferable (i) by will and by the laws of descent and distribution and (ii) during the lifetime of the Grantee, to the extent and in the manner authorized by the Administrator but only to the extent such transfers are made to family members, to family trusts, to family controlled entities, to charitable organizations, and pursuant to domestic relations orders or agreements, in all cases without payment for such transfers to the Grantee. Notwithstanding the foregoing, the Grantee may designate one or more beneficiaries of the Grantee's Award in the event of the Grantee's death on a beneficiary designation form provided by the Administrator.

(k) Time of Granting Awards. The date of grant of an Award shall for all purposes be the date on which the Administrator makes the determination to grant such Award, or such other date as is determined by the Administrator.

7. Award Exercise or Purchase Price, Consideration and Taxes.

(a) Exercise or Purchase Price. The exercise or purchase price, if any, for an Award shall be as follows:

(i) In the case of an Incentive Stock Option:

(A) granted to an Employee who, at the time of the grant of such Incentive Stock Option owns stock representing more than ten percent (10%) of the voting power of all classes of stock of the Company or any Parent or Subsidiary of the Company, the per Share exercise price shall be not less than one hundred ten percent (110%) of the Fair Market Value per Share on the date of grant; or

(B) granted to any Employee other than an Employee described in the preceding paragraph, the per Share exercise price shall be not less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(ii) In the case of a Non-Qualified Stock Option, the per Share exercise price shall be not less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(iii) In the case of Awards intended to qualify as Performance-Based Compensation, the exercise or purchase price, if any, shall be not less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(iv) In the case of SARs (other than with respect to Israeli Grantees), the base appreciation amount shall not be less than one hundred percent (100%) of the Fair Market Value per Share on the date of grant.

(v) In the case of other Awards, such price as is determined by the Administrator.

(vi) Notwithstanding the foregoing provisions of this Section 7(a), in the case of an Award issued pursuant to Section 6(d), above, the exercise or purchase price for the Award shall be determined in accordance with the provisions of the relevant instrument evidencing the agreement to issue such Award.

(b) Consideration. Subject to Applicable Laws, the consideration to be paid for the Shares to be issued upon exercise or purchase of an Award including the method of payment, shall be determined by the Administrator. In addition to any other types of consideration the Administrator may determine, the Administrator is authorized to accept as consideration for Shares issued under the Plan the following:

(i) cash;

(ii) check;

(iii) surrender of Shares or delivery of a properly executed form of attestation of ownership of Shares as the Administrator may require which have a Fair Market Value on the date of surrender or attestation equal to the aggregate exercise price of the Shares as to which said Award shall be exercised;

(iv) with respect to Options, payment through a broker-dealer sale and remittance procedure pursuant to which the Grantee (A) shall provide written instructions to a Company designated brokerage firm to effect the immediate sale of some or all of the purchased Shares and remit to the Company sufficient funds to cover the aggregate exercise price payable for the purchased Shares and (B) shall provide written directives to the Company to deliver the certificates for the purchased Shares directly to such brokerage firm in order to complete the sale transaction; or

(v) with respect to Options, payment through a "net exercise" such that, without the payment of any funds, the Grantee may exercise the Option and receive the net number of Shares equal to (i) the number of Shares as to which the Option is being exercised, multiplied by (ii) a fraction, the numerator of which is the Fair Market Value per Share (on such date as is determined by the Administrator) less the Exercise Price per Share, and the denominator of which is such Fair Market Value per Share (the number of net Shares to be received shall be rounded down to the nearest whole number of Shares);

(vi) any combination of the foregoing methods of payment.

The Administrator may at any time or from time to time, by adoption of or by amendment to the standard forms of Award Agreement described in Section 4(b)(iv), or by other means, grant Awards which do not permit all of the foregoing forms of consideration to be used in payment for the Shares or which otherwise restrict one or more forms of consideration.

(c) Taxes. No Shares shall be delivered under the Plan to any Grantee or other person until such Grantee or other person has made arrangements acceptable to the Administrator for the satisfaction of any non-U.S., federal, state, or local income and employment tax withholding obligations, including, without limitation, obligations incident to the receipt of Shares. Upon exercise or vesting of an Award the Company shall withhold or collect from the Grantee an amount sufficient to satisfy such tax obligations, including, but not limited to, by surrender of the whole number of Shares covered by the Award sufficient to satisfy the minimum applicable tax withholding obligations incident to the exercise or vesting of an Award (reduced to the lowest whole number of Shares if such number of Shares withheld would result in withholding a fractional Share with any remaining tax withholding settled in cash).

8. Exercise of Award.

(a) Procedure for Exercise; Rights as a Stockholder.

(i) Any Award granted hereunder shall be exercisable at such times and under such conditions as determined by the Administrator under the terms of the Plan and specified in the Award Agreement provided however that the standard vesting schedule for Israeli Grantees shall be as set forth in Section 20.

(ii) An Award shall be deemed to be exercised when written notice of such exercise has been given to the Company in accordance with the terms of the Award by the person entitled to exercise the Award and full payment for the Shares with respect to which the Award is exercised has been made, including, to the extent selected, use of the broker-dealer sale and remittance procedure to pay the purchase price as provided in Section 7(b).

(b) Exercise of Award Following Termination of Continuous Service. In the event of termination of a Grantee's Continuous Service for any reason other than Cause, Disability or death, such Grantee may, but only within twelve (12) months from the date of such termination (or such longer or shorter period as specified in the Award Agreement but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination or such other portion of the Grantee's Award as may be determined by the Administrator. To the extent that the Grantee's Award was unvested at the date of termination, or if Grantee does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(c) Exercise of Award Following Termination of Continuous Service for Cause. In the event of termination of a Grantee's Continuous Service for Cause, such Grantee may, but only within fourteen (14) days from the date of such termination (or such longer or shorter period as specified in the Award Agreement but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination or such other portion of the Grantee's Award as may be determined by the Administrator. To the extent that the Grantee's Award was unvested at the date of termination, or if Grantee does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(d) Disability of Grantee. In the event of termination of a Grantee's Continuous Service as a result of his or her Disability, such Grantee may, but only within twelve (12) months from the date of such termination (or such longer or shorter period as specified in the Award Agreement but in no event later than the expiration date of the term of such Award as set forth in the Award Agreement), exercise the portion of the Grantee's Award that was vested at the date of such termination or such other portion of the Grantee's Award as may be determined by the Administrator. To the extent that the Grantee's Award was unvested at the date of termination, or if Grantee does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(e) Death of Grantee. In the event of a termination of the Grantee's Continuous Service as a result of his or her death, or in the event of the death of the Grantee during the post-termination exercise periods following the Grantee's termination of Continuous Service specified in this Section 8, above, the Grantee's estate or a person who acquired the right to exercise the Award by bequest or inheritance may exercise the portion of the Grantee's Award that was vested as of the date of termination or such other portion of the Grantee's Award as may be determined by the Administrator, within twelve (12) months from the date of death (or such longer or shorter period as specified in the Award Agreement but in no event later than the expiration of the term of such Award as set forth in the Award Agreement). To the extent that, at the time of death, the Grantee's Award was unvested, or if the Grantee's estate or a person who acquired the right to exercise the Award by bequest or inheritance does not exercise the vested portion of the Grantee's Award within the time specified herein, the Award shall terminate.

(f) The holder of an Option shall have none of the rights of a stockholder with respect to the Shares subject to the Option until such shares are transferred to the holder (or the Trustee, if applicable) upon the exercise of the Option.

9. Conditions Upon Issuance of Shares.

(a) If at any time the Administrator determines that the delivery of Shares pursuant to the exercise, vesting or any other provision of an Award is or may be unlawful under Applicable Laws, the vesting or right to exercise an Award or to otherwise receive Shares pursuant to the terms of an Award shall be suspended until the Administrator determines that such delivery is lawful and shall be further subject to the approval of counsel for the Company with respect to such compliance. The Company shall have no obligation to effect any registration or qualification of the Shares under federal or state laws or other Applicable Laws.

(b) As a condition to the exercise of an Award, the Company may require the person exercising such Award make such representations and warranties which, in the opinion of the Company, are required to ensure that such exercise, or a subsequent sale or disposition of any Shares obtained upon such exercise, does not contravene any Applicable Law, including inter alia, representations and warranties at the time of any such exercise that the Shares are

being purchased only for investment and without any present intention to sell or distribute such Shares if, in the opinion of counsel for the Company, such a representation is required by any Applicable Laws.

(c) Unless otherwise set forth in an Award Agreement, Shares issued to a Grantee or the Trustee, as applicable, shall be subject to such restrictions as required by the appropriate securities' law and in the event that the Company's shares shall be registered for trading in any public market, Grantee's rights to sell the Shares may be subject to certain limitations (including a lock-up period), as will be requested by the Company or its underwriters, and the Grantee by executing an Award Agreement unconditionally agrees and accepts any such limitations and undertakes to further execute any agreement as may be requested by the Company or its underwriters from time to time.

10. Adjustments Upon Changes in Capitalization. Subject to any required action by the stockholders of the Company, the number of Shares covered by each outstanding Award, and the number of Shares which have been authorized for issuance under the Plan but as to which no Awards have yet been granted or which have been returned to the Plan, the exercise or purchase price of each such outstanding Award, the maximum number of Shares with respect to which Awards may be granted to any Grantee in any calendar year, as well as any other terms that the Administrator determines require adjustment shall be proportionately adjusted for (i) any increase or decrease in the number of issued Shares resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the Shares, or similar transaction affecting the Shares, (ii) any other increase or decrease in the number of issued Shares effected without receipt of consideration by the Company, or (iii) any other transaction with respect to Common Stock including a corporate merger, consolidation, acquisition of property or stock, separation (including a spin-off or other distribution of stock or property), reorganization, liquidation (whether partial or complete) or any similar transaction; provided, however that conversion of any convertible securities of the Company shall not be deemed to have been "effected without receipt of consideration." In the event of any distribution of cash or other assets to stockholders other than a normal cash dividend, the Administrator shall also make such adjustments as provided in this Section 10 or substitute, exchange or grant Awards to effect such adjustments (collectively "adjustments"). Any such adjustments to outstanding Awards will be effected in a manner that precludes the enlargement of rights and benefits under such Awards. In connection with the foregoing adjustments, the Administrator may, in its discretion, prohibit the exercise of Awards or other issuance of Shares, cash or other consideration pursuant to Awards during certain periods of time. Except as the Administrator determines, no issuance by the Company of shares of any class, or securities convertible into shares of any class, shall affect, and no adjustment by reason hereof shall be made with respect to, the number or price of Shares subject to an Award.

11. Corporate Transactions and Changes in Control.

(a) Termination of Award to Extent Not Assumed in Corporate Transaction. Effective upon the consummation of a Corporate Transaction, all outstanding Awards under the Plan shall terminate. However, all such Awards shall not terminate to the extent they are Assumed in connection with the Corporate Transaction.

(b) Acceleration of Award Upon Corporate Transaction or Change in Control.

(i) Corporate Transaction. Except as provided otherwise in an individual Award Agreement, in the event of a Corporate Transaction and:

(A) for the portion of each Award that is Assumed or Replaced, then such Award (if Assumed), the replacement Award (if Replaced), or the cash incentive program (if Replaced) automatically shall become fully vested, exercisable and payable and be released from any repurchase or forfeiture rights (other than repurchase rights exercisable at Fair Market Value) for all of the Shares (or other consideration) at the time represented by such Assumed or Replaced portion of the Award, immediately upon termination of the Grantee's Continuous Service if such Continuous Service is terminated by the successor company or the Company without Cause within twelve (12) months after the Corporate Transaction; and

(B) for the portion of each Award that is neither Assumed nor Replaced, such portion of the Award shall automatically become fully vested and exercisable and be released from any repurchase or forfeiture rights (other than repurchase rights exercisable at Fair Market Value) for all of the Shares (or other consideration) at the time represented by such portion of the Award, immediately prior to the specified effective date of such Corporate Transaction, provided that the Grantee's Continuous Service has not terminated prior to such date.

(ii) Change in Control. Except as provided otherwise in an individual Award Agreement, following a Change in Control (other than a Change in Control which also is a Corporate Transaction) and upon the termination of the Continuous Service of a Grantee if such Continuous Service is terminated by the Company

or Related Entity without Cause within twelve (12) months after a Change in Control, each Award of such Grantee which is at the time outstanding under the Plan automatically shall become fully vested and exercisable and be released from any repurchase or forfeiture rights (other than repurchase rights exercisable at Fair Market Value), immediately upon the termination of such Continuous Service.

(c) Effect of Acceleration on Incentive Stock Options. Any Incentive Stock Option accelerated under this Section 11 in connection with a Corporate Transaction or Change in Control shall remain exercisable as an Incentive Stock Option under the Code only to the extent the $100,000 dollar limitation of Section 422(d) of the Code is not exceeded.

12. Effective Date and Term of Plan. The Plan shall become effective upon the earlier to occur of its adoption by the Board or its approval by the stockholders of the Company. It shall continue in effect until December 31, 2028 unless sooner terminated. Subject to Section 17, below, and Applicable Laws, Awards may be granted under the Plan upon its becoming effective.

13. Amendment, Suspension or Termination of the Plan.

(a) The Board may at any time amend, suspend or terminate the Plan; provided, however, that no such amendment shall be made without the approval of the Company's stockholders to the extent such approval is required by Applicable Laws, or if such amendment would lessen the stockholder approval requirements of Section 4(b)(vi) or this Section 13(a).

(b) No Award may be granted during any suspension of the Plan or after termination of the Plan.

(c) No suspension or termination of the Plan (including termination of the Plan under Section 11, above) shall adversely affect any rights under Awards already granted to a Grantee.

14. Reservation of Shares.

(a) The Company, during the term of the Plan, will at all times reserve and keep available such number of Shares as shall be sufficient to satisfy the requirements of the Plan.

(b) The inability of the Company to obtain authority from any regulatory body having jurisdiction, which authority is deemed by the Company's counsel to be necessary to the lawful issuance and sale of any Shares hereunder, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority shall not have been obtained.

15. No Effect on Terms of Employment/Consulting Relationship. The Plan shall not confer upon any Grantee any right with respect to the Grantee's Continuous Service, nor shall it interfere in any way with his or her right or the right of the Company or any Related Entity to terminate the Grantee's Continuous Service at any time, with or without cause, including but not limited to, Cause, and with or without notice. The ability of the Company or any Related Entity to terminate the employment of a Grantee who is employed at will is in no way affected by its determination that the Grantee's Continuous Service has been terminated for Cause for the purposes of this Plan.

16. No Effect on Retirement and Other Benefit Plans. Except as specifically provided in a retirement or other benefit plan of the Company or a Related Entity, Awards shall not be deemed compensation for purposes of computing benefits or contributions under any retirement plan of the Company or a Related Entity, and shall not affect any benefits under any other benefit plan of any kind or any benefit plan subsequently instituted under which the availability or amount of benefits is related to level of compensation. The Plan is not a "Pension Plan" or "Welfare Plan" under the Employee Retirement Income Security Act of 1974, as amended.

17. Stockholder Approval. The grant of Incentive Stock Options under the Plan shall be subject to approval by the stockholders of the Company within twelve (12) months before or after the date the Plan is adopted excluding Incentive Stock Options issued in substitution for outstanding Incentive Stock Options pursuant to Section 424(a) of the Code. Such stockholder approval shall be obtained in the degree and manner required under Applicable Laws. The Administrator may grant Incentive Stock Options under the Plan prior to approval by the stockholders, but until such approval is obtained, no such Incentive Stock Option shall be exercisable. In the event that stockholder approval is not obtained within the twelve (12) month period provided above, all Incentive Stock Options previously granted under the Plan shall be exercisable as Non-Qualified Stock Options.

18. Unfunded Obligation. Grantees shall have the status of general unsecured creditors of the Company. Any amounts payable to Grantees pursuant to the Plan shall be unfunded and unsecured obligations for all purposes, including, without limitation, Title I of the Employee Retirement Income Security Act of 1974, as amended. Neither the Company nor any Related Entity shall be required to segregate any monies from its general funds, or to create any trusts, or establish any special accounts with respect to such obligations. The Company shall retain at all times beneficial ownership of any investments, including trust investments, which the Company may make to fulfill its payment obligations hereunder. Any investments or the creation or maintenance of any trust or any Grantee account shall not create or constitute a trust or fiduciary relationship between the Administrator, the Company or any Related Entity and a Grantee, or otherwise create any vested or beneficial interest in any Grantee or the Grantee's creditors in any assets of the Company or a Related Entity. The Grantees shall have no claim against the Company or any Related Entity for any changes in the value of any assets that may be invested or reinvested by the Company with respect to the Plan.

19. Construction. Captions and titles contained herein are for convenience only and shall not affect the meaning or interpretation of any provision of the Plan. Except when otherwise indicated by the context, the singular shall include the plural and the plural shall include the singular. Use of the term "or" is not intended to be exclusive, unless the context clearly requires otherwise.

20. Israeli Grantees. This Section shall apply only to Israeli Grantees and is intended to enable the Company to grant Awards under the Plan pursuant and subject to Section 102 and Section 3(I) of the Tax Ordinance. Accordingly, the Plan is designated to comply with the Tax Ordinance and the rules, regulations and orders or procedures promulgated thereunder from time to time, as amended or replaced from time to time and shall be submitted to the ITA as required thereunder.

In any case of contradiction, whether explicit or implied, between the provisions of this Section and the Plan, the provisions set out in this Section shall prevail unless the Administrator decides otherwise to ensure compliance with the Tax Ordinance and other Applicable Laws.

(a) Eligibility. 102 Options may be granted only to Israeli Employees. Non-Employees may only be granted 3(I) Options. The grant of an Award hereunder shall neither entitle the Grantee to participate nor disqualify the Israeli Grantee from participating in, any other grant of Awards pursuant to the Plan or any other option or stock plan of the Company or any Related Company.

(b) Grant of Awards in Trust

(i) Grants Made Under Section 102.

The Company may designate 102 Options as Trustee 102 Options or Non-Trustee 102 Options. The designation of Non-Trustee 102 Options and Trustee 102 Options shall be subject to the terms and conditions set forth in Section 102 of the Tax Ordinance and the regulations promulgated thereunder.

(ii) Grant of Trustee 102 Options.

(1) The grant of the Trustee 102 Options shall be made under the Plan and shall be conditional upon the approval of the Plan by the ITA. Trustee 102 Options may be granted at any time after the passage of thirty (30) days following the delivery by the Company to the ITA of a notice pertaining to the appointment of the Trustee and the adoption of the Plan, unless otherwise determined by the ITA. Options which shall be granted pursuant to Section 102 and/or any Shares issued upon exercise of such Options and/or other shares received subsequently following any realization of rights, shall be issued to the Trustee. Each Israeli Grantee in respect of whom a Trustee 102 Option is granted and held in trust by the Trustee shall be referred to as a "beneficial optionee" hereunder.

(2) Trustee 102 Option(s) may either be classified as Capital Gain Option(s) or Ordinary Income Option(s):

(A) Trustee 102 Option(s) elected and designated by the Company to qualify under the capital gain tax treatment in accordance with the provisions of Section 102(b)(2) shall be referred to herein as "Capital Gain Option(s)" or "CGO".

(B) Trustee 102 Option(s) elected and designated by the Company to qualify under the ordinary income tax treatment in accordance with the provisions of Section 102(b)(1) shall be referred to herein as "Ordinary Income Option(s)" or "OIO".

(3) The Company's election of the type of Trustee 102 Options as CGO or OIO granted to Employees (the "Election") shall be appropriately filed with the ITA 30 days before the date of grant of a Trustee 102 Option, unless otherwise determined by the ITA. Such Election shall become effective beginning the first date of grant of a Trustee 102 Option under this Plan and shall remain in effect until the end of the year following the year during which the Company first granted Trustee 102 Options. The Election shall obligate the Company to grant only the type of Trustee 102 Option it has elected, and shall apply to all Israeli Grantees who were granted Trustee 102 Options during the period indicated herein or therein, all in accordance with the provisions of Section 102(g) of the Tax Ordinance. Notwithstanding, such Election shall not prevent the Company from granting Non-Trustee 102 Options simultaneously.

(4) All Trustee 102 Options must be held in trust by and issued on the name of the Trustee, as described below.

(5) With respect to Trustee 102 Options, the provisions of the Plan and/or an Award Agreement shall be subject to the provisions of Section 102 and the ITA's permit, and the said provisions and permit shall be deemed an integral part of this Section and of the Award Agreement for the respective Grantees thereof. Any provision of Section 102 and/or the said permit which is necessary in order to receive and/or to keep any tax benefit pursuant to Section 102, which is not expressly specified in the Plan or the Award Agreement, shall be considered binding upon the Company and the Israeli Grantee.

(iii) Issuance to Trustee.

(1) All Trustee 102 Options granted under the Plan and/or any Shares allocated or issued upon exercise of such Trustee 102 Options and/or other and all rights deriving from or in connection therewith, including, without limitation, in accordance with Section 10 above or any bonus shares or stock dividends issued in connection therewith shall be granted by the Company to the Trustee, and the Trustee shall hold each such Trustee 102 Option and the Shares issued upon exercise thereof in trust for such period of time as required by Section 102 or any regulations, rules or orders or procedures promulgated thereunder (the "Holding Period"), for the benefit of the Grantees in respect of whom such Trustee 102 Option was granted. All certificates representing Shares issued to the Trustee under the Plan shall be deposited with the Trustee, and shall be held by the Trustee until such time that such Shares are released from the Trust as herein provided.

(2) In event the requirements for Trustee 102 Options are not met for any reason whatsoever, then the Trustee 102 Options may be treated as Non-Trustee 102 Options, all in accordance with the provisions of Section 102 and regulations promulgated thereunder.

(3) With respect to any Trustee 102 Option, subject to the provisions of Section 102 and any rules or regulations or orders or procedures promulgated thereunder, an Israeli Grantee shall not be entitled to sell or release from Trust the Trustee 102 Option, the Shares received upon the exercise of such Option and/or any right deriving from or in connection therewith, including, without limitation, in accordance with Section 10 above or any bonus shares or stock dividends issued in connection therewith, until the later of: (i) the lapse of the Holding Period required under Section 102, and (ii) the vesting of such Options set forth in the respective Award Agreement (such later date being hereinafter referred to as the "Release Date"). Notwithstanding the foregoing, if such sale or release occurs during the Holding period, the provisions of Section 102 and the rules or regulations promulgated thereunder shall apply and any expenses and/or tax consequences therefrom shall be borne by the Israeli Grantee.

(4) Subject to the terms hereof, at any time after the Release Date with respect to any Trustee 102 Options or Shares the following shall apply:

(A) Trustee 102 Options granted, and/or Shares or rights issued to the Trustee shall continue to be held by the Trustee, on behalf of the beneficial optionee. From and after the Release Date, upon the written request of any beneficial optionee, the Trustee shall release from the Trust the Trustee 102 Options granted, and/or the Shares or rights issued, on behalf of such beneficial optionee, by executing and delivering to the Company such instrument(s) as the Company may require, giving due notice of such release to such beneficial optionee, provided, however, that the Trustee shall not so release any such Trustee 102 Options and/or Shares and/or rights to such beneficial optionee unless the latter, prior to, or concurrently with, such release, provides the Trustee with evidence, satisfactory in form and substance to the Trustee, that all taxes, if any, required to be paid upon such release have, in fact, been paid.

(B) Alternatively, from and after the Release Date, upon the written instructions of the beneficial optionee to sell any Shares and rights issued upon exercise of Trustee 102 Options, the Trustee shall use its best efforts to effect such sale and shall transfer such Shares to the purchaser thereof concurrently with the receipt, or after having made suitable arrangements to secure the payment, of the purchase price in such transactions. The Trustee shall withhold from such proceeds any and all taxes required to be paid in respect of such sale, shall remit the amount so withheld to the appropriate tax authorities and shall pay the balance thereof directly to the beneficial optionee, reporting to such beneficial optionee and to the Company the amount so withheld and paid to said authorities.

(C) Notwithstanding the foregoing, in the event the underwriters of securities of the Company impose restrictions on the transferability of the Shares during a lock-up period, the beneficial optionee shall not be entitled to release from Trust the Trustee 102 Options granted and/or the Shares issued and/or to instruct the Trustee to effect a sale of same, for as long as the restrictions are in effect. In the event the Trustee 102 Options granted and/or the Shares issued have been released from trust the restrictions imposed on the transferability of same shall nevertheless apply to said optionee's Trustee 102 Options and/or Shares in the same manner. Consequently, the Israeli Grantee shall sign any documents required in order to effect the restrictions, for as long as the restrictions are in effect.

(D) Upon receipt of the Award, the Israeli Grantee will sign an undertaking to release the Trustee from any liability in respect of any action or decision duly taken and bona fide executed in relation with the Plan, or any Option or Share or rights granted to same thereunder. The Trustee may establish additional terms and conditions in connection with Awards held in trust by the Trustee.

(iv) Grant of Non-Trustee 102 Options

(1) Awards granted pursuant to this subsection are intended to constitute Non-Trustee 102 Options and shall be subject to the general terms and conditions of the Plan and Section 20, except for provisions of the Plan applying to Trustee 102 Awards or Options under a different tax law or regulation.

(2) With respect to Non-Trustee 102 Options, if the Grantee ceases to be employed by or of service to the Company or a Related Company, the Grantee may be required to extend to the Company a security or guarantee for the payment of tax due at the time of sale of Shares or other rights, all in accordance with the provisions of Section 102 and the rules, regulation or orders promulgated thereunder.

(v) Grants Made Under Section 3(I). Awards granted pursuant to this subsection are intended to constitute 3(I) Options and shall be subject to the general terms and conditions of the Plan and Section 20 thereof, except for said provisions of the Plan applying to Awards under a different tax law or regulation. The Administrator may choose to deposit the Awards granted pursuant to Section 3(I) of the Tax Ordinance with a trustee. In such event, said trustee shall hold such Option in trust, until exercised by the Grantee, pursuant to the Company's instructions from time to time. If determined by the Administrator, the trustee shall be responsible for withholding any taxes to which a Grantee become liable upon the exercise of Options.

(c) Award Agreement. Without derogating from the powers of the Administrator under the Plan, the Administrator shall adopt the form of Award Agreement for Israeli Grantees in form acceptable by the ITA and in compliance with the Tax Ordinance. The Award Agreement shall further indicate the type of Options (102, 3(I), Trustee, Non-Trustee etc.) granted thereunder.

(d) Vesting. Without derogating from the terms of any Award Agreement or the discretionary authority of the Administrator, the standard vesting for Options to Israeli Grantees shall be as follows:

(i) Twenty five percent (25%) of the Options granted under each Award Agreement shall vest on the end of the first year of Continuous Service following the vesting commencement date determined by the Administrator and if not specified the date of the grant of an Option (the "First Anniversary"); and

(ii) The remaining 75% of the Options shall vest on a quarterly basis over a period of three years commencing as of the First Anniversary in twelve (12) equal portions subject to Continuous Service of the Grantee.

(e) With respect to all Shares (in contrast to unexercised Options) allocated or issued upon the exercise of Options by the Israeli Grantee, the Grantee shall be entitled to receive dividends in accordance with the

quantity of such Shares, subject however to any applicable taxation on distribution of dividends. Subject to the Tax Ordinance and any restrictions imposed by the Trustee or the ITA, during the period in which Shares are held by the Trustee on behalf of the Israeli Grantee, the cash dividends paid with respect thereto shall be paid directly to the Grantee after deduction of withholding tax applicable thereto.

(f) Without derogating from anything in the Plan, to the extent permitted by Applicable Laws, any tax consequences, attributable to the Israeli Grantee, arising from the grant or exercise of any Option, from the payment for Shares covered thereby or from any other event or act (of the Company, a Related Company, the Trustee or the Grantee), hereunder, shall be borne solely by the Grantee. The Company and/or or a Related Company and/or the Trustee shall withhold taxes according to the requirements under the Applicable Laws, rules, and regulations, including withholding taxes at source. Furthermore, to the extent permitted by Applicable Law, the Grantee shall agree to indemnify the Company and/or a Related Company and/or the Trustee and hold them harmless against and from any and all liability for any such tax or interest or penalty thereon, including without limitation, liabilities relating to the necessity to withhold, or to have withheld, any such tax from any payment made to the Grantee. The Administrator and/or the Trustee shall not be required to release any Share certificate to a Grantee until all required payments have been fully made.

The Plan, to the extent applicable to Israeli Grantees, shall be governed by and construed and enforced in accordance with the laws of the State of Israel applicable to contracts made and to be performed therein, without giving effect to the principles of conflict of laws. The competent courts of Tel-Aviv, Israel shall have sole jurisdiction in any matters pertaining to Israeli Grantees.

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: August 7, 2023

/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: August 7, 2023

/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 June 30, 2023 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: August 7, 2023

/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 June 30, 2023 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: August 7, 2023

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