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

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

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 May 1, 2024, approximately 73,316,084 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)

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 27,209	$ 23,634
Short-term bank deposits	21,278	20,926
Accounts receivable – Trade	3,759	5,272
Other assets	812	1,055
Inventories	22,346	19,045
Total current assets	$ 75,404	$ 69,932
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 531	$ 528
Property and equipment, net	4,781	4,973
Deferred income tax asset	3,230	3,092
Operating lease right of use assets	5,879	5,909
Total assets	$ 89,825	$ 84,434
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,146	$ 4,320
Other	18,770	19,550
Operating lease liabilities	1,453	1,409
Contracts liability	11,039	-
Convertible notes	20,420	20,251
Total current liabilities	$ 54,828	$ 45,530
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 712	$ 714
Operating lease liabilities	4,499	4,621
Total long term liabilities	$ 5,211	$ 5,335
Total liabilities	$ 60,039	$ 50,865
COMMITMENTS		
STOCKHOLDERS' EQUITY	29,786	33,569
Total liabilities and stockholders' equity	$ 89,825	$ 84,434

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)

	Three Months Ended	
	March 31, 2024	March 31, 2023
REVENUES FROM SELLING GOODS	$ 3,677	$ 5,066
REVENUES FROM LICENSE AND R&D SERVICES	71	4,522
TOTAL REVENUE	3,748	9,588
COST OF GOODS SOLD	(2,602)	(3,085)
RESEARCH AND DEVELOPMENT EXPENSES	(2,887)	(5,847)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(3,115)	(3,115)
OPERATING LOSS	(4,856)	(2,459)
FINANCIAL EXPENSES	(390)	(649)
FINANCIAL INCOME	513	172
FINANCIAL INCOME (EXPENSES), NET	123	(477)
LOSS BEFORE TAX BENEFIT (TAXES ON INCOME)	(4,733)	(2,936)
TAX BENEFIT (TAXES ON INCOME)	138	(195)
NET LOSS FOR THE PERIOD	$ (4,595)	$ (3,131)
LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED	$ (0.06)	$ (0.05)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE (Basic and Diluted):	73,036,569	57,480,009

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, 2023	**53,790,167**	**$ 54**	**$ 379,167**	**$ (389,861)**	**$ (10,640)**
Changes during the three-month period ended March 31, 2023:					
Issuance of common stock under the Sales Agreement, net	8,212,482	8	14,225		14,233
Share-based compensation related to stock options			453		453
Share-based compensation related to restricted stock awards			93		93
Net loss for the period				(3,131)	(3,131)
Balance at March 31, 2023	**62,002,649**	**$ 62**	**$ 393,938**	**$ (392,992)**	**$ 1,008**
Balance at January 1, 2024	**72,952,124**	**$ 73**	**$ 415,045**	**$ (381,549)**	**$ 33,569**
Changes during the three-month period ended March 31, 2024:					
Initial adoption of ASU 2020-06			(393)	224	(169)
Share-based compensation related to stock options			500		500
Share-based compensation related to restricted stock awards	100,000	*	481		481
Net loss for the period				(4,595)	(4,595)
Balance at March 31, 2024	**73,052,124**	**$ 73**	**$ 415,633**	**$ (385,920)**	**$ 29,786**

*Represents an amount equal to less than $1.

(1) Common stock, $0.001 par value; Authorized – as of March 31, 2024 and December 31, 2023 – 185,000,000 shares.

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

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

	Three Months Ended	
	March 31, 2024	March 31, 2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,595)	$ (3,131)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation	981	546
Depreciation	322	280
Financial income, net	(471)	(91)
Changes in accrued liability for employee rights upon retirement	8	19
Changes in deferred tax asset	(138)	-
Loss (gain) on amounts funded in respect of employee rights upon retirement	(3)	1
Amortization of debt issuance costs and debt discount		80
Changes in operating assets and liabilities:		
Increase (decrease) in contracts liability	11,039	(1,388)
Decrease in accounts receivable-trade and other assets	1,746	3,823
Changes in operating lease right of use assets, net	14	9
Increase in inventories	(3,301)	(3,499)
Increase (decrease) in accounts payable and accruals	(1,414)	353
Net cash provided by (used in) operating activities	$ 4,188	$ (2,998)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of short-term deposits		$ 5,000
Purchase of property and equipment	$ (598)	(248)
Amounts funded in respect of employee rights upon retirement, net	(8)	(20)
Net cash provided by (used in) investing activities	$ (606)	$ 4,732
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock under the Sales Agreement, net	$ -	$ 14,233
Net cash provided by financing activities	$ -	$ 14,233
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (7)	$ (42)
NET INCREASE IN CASH AND CASH EQUIVALENTS	3,575	15,925
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	23,634	17,111
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 27,209	$ 33,036

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

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

(Continued) – 2

	Three Months Ended	
	March 31, 2024	March 31, 2023
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 146	$ 326
Operating lease right of use assets obtained in exchange for new operating lease liabilities	$ 186	$ 312
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$ 766	$ 1,078
Interest received	$ 33	$ 78

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

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

Protalix BioTherapeutics, Inc. (collectively with its subsidiaries, the "Company") and its wholly-owned subsidiaries, Protalix Ltd. and Protalix B.V. (collectively, the "Subsidiaries"), are biopharmaceutical companies focused on the development and commercialization of recombinant therapeutic proteins based on the Company's proprietary ProCellEx® protein expression system ("ProCellEx"). To date, the Company has successfully developed two enzyme replacement therapies (ERTs); Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease and Elelyso® (taliglucerase alfa) for the treatment of adult patients with Gaucher disease. Elfabrio, which the Company referred to as PRX-102 during its development stage, has been approved for marketing in the United States, the European Union, Great Britain, Switzerland and Israel. The Company has partnered with Chiesi Farmaceutici S.p.A. ("Chiesi") for the development and commercialization of Elfabrio.

The Company has licensed the rights to commercialize Elelyso worldwide (other than Brazil) to Pfizer Inc. ("Pfizer"), and in Brazil to Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health (the "Brazilian MoH"). Elelyso is marketed as BioManguinhos alfataliglicerase in Brazil.

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

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 a confirmed diagnosis of 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 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 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 the Company's 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.

PROTALIX BIOTHERAPEUTICS, INC.
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(Unaudited)

From time to time, and as Elfabrio is approved for marketing in different jurisdictions, participants withdraw from the open label extension studies. Some of the withdrawals transfer to a commercial setting, others withdraw for other reasons.

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").

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

The 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.

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

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

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

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

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

On March 21, 2023, the first patient was dosed in the Company's phase I First-in-Human clinical trial of PRX-115. This study was designed to be conducted in approximately 56 adult male and female subjects in the dose escalation phase with seven sequential dosing cohorts, each composed of eight subjects (six active and two placebo). As of March 31, 2024, 56 patients have been dosed in this study. The Company has decided to expand the study by adding an eighth cohort with eight new subjects and to commence preparations for a phase II clinical trial of PRX-115.

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").

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 thereby completing the ATM program under said agreement.

PROTALIX BIOTHERAPEUTICS, INC.
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(Unaudited)

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 the Agent, ATM Shares having an aggregate offering price of up to $20.0 million. As of March 31, 2024, 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.

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.

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 product from Protalix, subject to certain terms and conditions. The consideration for Protalix Ltd. is based on the drug product supplied to Chiesi and the average selling price of the drug product in the relevant territory multiplied by tiered payments as described in the relevant agreement. Under the Chiesi Ex-US Agreement, the price payable to the Company for drug product supplied is based on a range of 15% to 35% of the average selling price of the drug product in the applicable territory, and under the Chiesi US Agreement, such price is based on a range of 15% to 40% of the average selling price of the drug product in the United States.

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 pegunigalsidase alfa in connection with the commercial fill/finish services. Under the F/F Agreement, and, following relevant technology and technical information transfer activities, Chiesi agreed, among other things, to provide the Company with commercial fill/finish services for pegunigalsidase alfa, including to support the anticipated global launch of pegunigalsidase alfa. 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.

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 (the "Brazil Agreement") with Fiocruz for BioManguinhos alfataliglicerase. Fiocruz's purchases of BioManguinhos alfataliglicerase to date have been significantly below certain agreed-upon purchase milestones and, accordingly, the Company has the right to terminate the Brazil Agreement. Notwithstanding the termination right, the Company is, at this time, continuing to

PROTALIX BIOTHERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
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supply BioManguinhos alfataliglicerase to Fiocruz and patients continue to be treated with BioManguinhos alfataliglicerase in Brazil.

Because the Company's operations are conducted in the State of Israel, the business and operations may be directly affected by economic, political, geopolitical and military conditions in Israel. In October 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel attacking a number of civilian and military targets. At the same time, clashes between Israel and Hezbollah in Lebanon have increased. In response, Israel's security cabinet declared war against the Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the attacks by Hamas and Hezbollah, and Israel's defensive measures, may result in a greater regional conflict. Since the outbreak of the war, other regional actors, including Iran, have taken military action against Israel. It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on the Company's business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing, and could disrupt certain of the Company's business and operations, among others. The Company has elected to store manufactured drug substance in multiple locations, both within and outside of Israel, to mitigate the risk of loss due to the military operations. As of the issuance of these financial statements, the impact of the war has not had an adverse effect on the Company's operations.

The Company expects to continue to incur significant expenditures in the near future due to research and developments efforts with respect to the product candidates. Under the terms of the Company's outstanding 7.50% Senior Secured Convertible Notes due September 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 March 31, 2024, the Company is in compliance with all such covenants. The Company believes that its cash, cash equivalents and short-term bank deposits as of March 31, 2024 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, 2023, filed by the Company with the U.S. Securities and Exchange Commission (the "Commission"). The comparative balance sheet at December 31, 2023 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, 2023.

c. Loss per share

The Company calculates loss per share by dividing the net loss by the weighted average number of shares of Common Stock outstanding during each period.

Diluted earnings per share is calculated by dividing the net loss 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

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

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.

Diluted loss per share does not include 36,292,208 shares of Common Stock underlying outstanding stock options, warrants and the 2024 Notes for the three months ended March 31, 2023 because the effect would be anti-dilutive. Diluted loss per share does not include 31,839,345 shares of Common Stock underlying outstanding stock options, warrants and the 2024 Notes for the three months ended March 31, 2024 because the effect would be anti-dilutive.

d. Convertible notes

Prior to January 1, 2024, the Company accounted for its outstanding convertible notes using the guidance set forth in the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815 which required that the Company determine whether the embedded conversion option must be separated from the other features of the applicable note instrument and accounted for separately. ASC 470-20 regarding debt with conversion and other options requires the issuer of a convertible debt instrument that may be settled in cash upon conversion to separately account for the liability (debt) and equity (conversion option) components of the instrument in a manner that reflects the issuer's nonconvertible debt borrowing rate. The Company's outstanding 2024 Notes were accounted for as a liability (debt) and equity component (conversion option) as the convertible notes may be settled wholly or partly in cash, at the option of the Company, when converted.

In August 2020, the FASB issued ASU 2020-06 "Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815 – 40)" ("ASU 2020-06"). ASU 2020-06 simplifies the accounting for convertible instruments by removing certain separation models in ASC 470-20, Debt—Debt with Conversion and Other Options, for convertible instruments. ASU 2020-06 updates the guidance on certain embedded conversion features that are not required to be accounted for as derivatives under Topic 815, Derivatives and Hedging, or that do not result in substantial premiums accounted for as paid-in capital, such that those features are no longer required to be separated from the host contract. The convertible debt instruments will be accounted for as a single liability measured at amortized cost. This will also result in the interest expense recognized for convertible debt instruments to be typically closer to the coupon interest rate when applying the guidance in Topic 835. On January 1, 2024, the Company adopted ASU 2020-06 using the modified retrospective method of adoption. Under this method, the Company applied the guidance to the 2024 Notes at the adoption date and was required to make an adjustment to January 1, 2024, opening accumulated deficit balance and additional paid in capital. The prior period consolidated financial statements have not been retrospectively adjusted and continue to be reported under the accounting standards in effect for those periods. Under ASU 2020-06, the 2024 Notes (debt and conversion option) are accounted for as a liability. The impact to the Company's consolidated balance sheet as of December 31, 2023 resulting from its adoption of ASU 2020-06 is as follows:

(U.S. dollars in thousands)	**As Reported December 31, 2023**	**Updated January 1, 2024**	**Effect of Change**
Convertible notes	$ 20,251	$ 20,420	$ 169
Additional paid in capital	415,045	414,652	(393)
Accumulated deficit	381,549	381,325	224

The impact of adoption of ASU 2020-06 on the condensed consolidated balance sheet as of March 31, 2024 and on the Company's condensed consolidated statement of operations for the three months ended March 31, 2024 was as follows:

PROTALIX BIOTHERAPEUTICS, INC.
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(Unaudited)

(U.S. dollars in thousands)	As Reported March 31, 2024	Balances without Adoption of ASU 2020-06	Effect of Change
Financial expense	$ 382	$ 444	(62)
Convertible notes	20,420	20,313	(107)
Additional paid in capital	415,633	416,026	393
Accumulated deficit	385,920	386,206	(286)

e. New accounting pronouncements

Recently adopted accounting pronouncements

ASU 2020-06, which was issued by the FASB in August 2020 and adopted by the Company in January 2024, simplifies the accounting for certain financial instruments with characteristics of both liability and equity, including convertible instruments and contracts on an entity's own equity. The amendments to this guidance are effective for fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. See Note 1(d).

Recently issued accounting pronouncements, not yet adopted

In December 2023, the FASB issued ASU 2023-09 "Income Taxes (Topic 740): Improvements to Income Tax Disclosures." This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the United States and in foreign jurisdictions. ASU 2023-09 is effective for fiscal years beginning after December 15, 2024 on a prospective basis. Early adoption is permitted, with the option to apply the standard retrospectively. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements disclosures.

In November 2023, the FASB issued ASU 2023-07 "Segment Reporting: Improvements to Reportable Segment Disclosures." This guidance expands public entities' segment disclosures primarily by requiring disclosure of significant segment expenses that are regularly provided to the chief operating decision maker and included within each reported measure of segment profit or loss, an amount and description of its composition for other segment items, and interim disclosures of a reportable segment's profit or loss and assets. Public entities with a single reportable segment are required to provide the new disclosures and all of the disclosures required under ASC 280. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The amendments are required to be applied retrospectively to all prior periods presented in an entity's financial statements. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements and related disclosures.

NOTE 2 - INVENTORIES

Inventories at March 31, 2024 and December 31, 2023 consisted of the following:

(U.S. dollars in thousands)	March 31, 2024	December 31, 2023
Raw materials	$ 4,024	$ 4,176
Work in progress	9,169	9,055
Finished goods	9,153	5,814
Total inventory	$ 22,346	$ 19,045

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NOTE 3 – FAIR VALUE MEASUREMENT

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

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

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

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

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

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

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

Based on a Level 3 measurement, as of March 31, 2024, the fair value of the $20.4 million aggregate principal amount of the Company's outstanding 2024 Notes is approximately $21.2 million. The value of these notes was estimated by implementing the binomial model. The liability component was valued based on the Income Approach. The following parameters were used:

	2024 Notes
Stock price (USD)	1.26
Expected term	0.42
Risk free rate	5.16 %
Volatility	67.06 %
Yield	12.06 %

NOTE 4 – REVENUES

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

(U.S. dollars in thousands)	Three Months Ended March 31, 2024	2023
Pfizer	$ 1,127	$ 2,266
Brazil	$ 2,550	$ 2,800
Total revenues from selling goods	$ 3,677	$ 5,066
Revenues from license and R&D services	$ 71	$ 4,522

NOTE 5 – STOCK TRANSACTIONS

On January 15, 2024, the Company granted, with the approval of the Company's compensation committee, 100,000 shares of restricted Common Stock, in the aggregate, to certain of the Company's employees under the Company's Amended and Restated 2006 Employee Stock Incentive Plan, as amended (the "Plan"). All such shares of restricted Common Stock vest over a three-year period in 12 equal quarterly increments. The Company estimated the fair value of the restricted stock on the date of grant to be approximately $0.2 million.

PROTALIX BIOTHERAPEUTICS, INC.
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(Unaudited)

NOTE 6 – TAXES ON INCOME

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

(U.S. dollars in thousands)	Three Months Ended March 31, 2024	Three Months Ended March 31, 2023
Current taxes on income	-	$ 195
Deferred taxes on income	$ (138)	-
Total taxes on income (tax benefit)	$ (138)	$ 195

The Company had an effective tax rate of (3)% for the three months ended March 31, 2024, compared to an effective tax rate of 7% for the three months ended March 31, 2023. For the three months ended March 31, 2024, the difference between the Company's effective tax rate and the U.S. federal statutory rate of 21% was the result of forecasted profits derived primarily from U.S. taxable GILTI income mainly due to Section 174 of the U.S. Tax Cuts and Jobs Act, which was enacted in December 2017 (the "TCJA").

NOTE 7 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Balance sheets:

(U.S. dollars in thousands)	March 31, 2024	December 31, 2023
Accounts payable and accruals – other:		
Payroll and related expenses	$ 2,502	$ 1,437
Interest payable	128	511
Provision for vacation	1,696	1,605
Accrued expenses	8,451	9,009
Royalties payable	110	637
Income tax payable	2,876	2,876
Sales reserve	2,861	2,861
Property and equipment suppliers	146	614
	$ 18,770	$ 19,550

NOTE 8 – SUBSEQUENT EVENTS

1) On May 9, 2024 the Company collected approximately $1.1 million from sales to Pfizer and on May 8, 2024 the Company collected approximately $2.6 million from sales to Brazil.

2) On April 1, 2024, the Company granted, with the approval of the Company's compensation committee, 263,960 shares of fully-vested restricted Common Stock, in the aggregate, to its President and Chief Executive Officer under the Plan. The Company estimated the fair value of the restricted stock on the date of grant to be approximately $0.3 million.

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, 2023. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements within the meanings of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to our company, our subsidiaries or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements 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® (pegunigalsidase alfa-iwxj), our approved product for the treatment of adult patients with Fabry disease;
- risks relating to Elfabrio's market acceptance, competition, reimbursement and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product;
- the possible disruption of our operations due to the war declared by Israel's security cabinet against the Hamas terrorist organization located in the Gaza Strip, the military campaign against the Hezbollah and other 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, and the risk that the current hostilities will result in a greater regional conflict;
- risks related to the regulatory approval and commercial success of our other product and product candidates, if approved;
- risks related to our expectations with respect to the projected market for our products and product candidates;
- failure or delay in the commencement or completion of our preclinical studies and clinical trials, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; inability to monitor patients adequately during or after treatment; and/or lack of sufficient funding to finance our clinical trials;
- delays in the approval or potential rejection of any applications we file with the FDA, EMA or other health regulatory authorities for our other product candidates, and other risks relating to the review process;
- 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 or debt markets to raise capital to finance future research and development activities, general and administrative expenses and working capital;
- risks relating to our evaluation and pursuit of strategic partnerships;

- the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy and that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics;
- risks relating to our ability to manage our relationship with our collaborators, distributors or partners, including, but not limited to, Pfizer and Chiesi;
- risks related to the amount and sufficiency of our cash, cash equivalents and short-term bank deposits;
- risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness;
- risks relating to changes to interim, topline or preliminary data from clinical trials that we announce or publish;
- 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; and
- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere.

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

Recent Company Developments

In May 2024, we decided to expand our phase I First-in-Human clinical trial of PRX-115 by adding an eighth cohort with eight new patients. We also decided to commence preparations for a phase II clinical trial of PRX-115.

ProCellEx: Our Proprietary Protein Expression System

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

ProCellEx consists of a comprehensive set of proprietary technologies and capabilities, including the use of advanced genetic engineering and plant cell culture technology, enabling us to produce complex, proprietary, and biologically equivalent proteins for a variety of human diseases. Our protein expression system facilitates the creation and selection of high-expressing, genetically-stable cell lines capable of expressing recombinant proteins. The system plays an important role in the execution of our corporate strategy as its allows us to develop and produce tailored complex recombinant therapeutic proteins and to genetically engineer and/or chemically

modify such proteins pre- and/or post-production. The engineering and modification of the therapeutic proteins have the potential to provide added clinical benefits by improving the biological characteristics (e.g., glycosylation, half-life, immunogenicity).

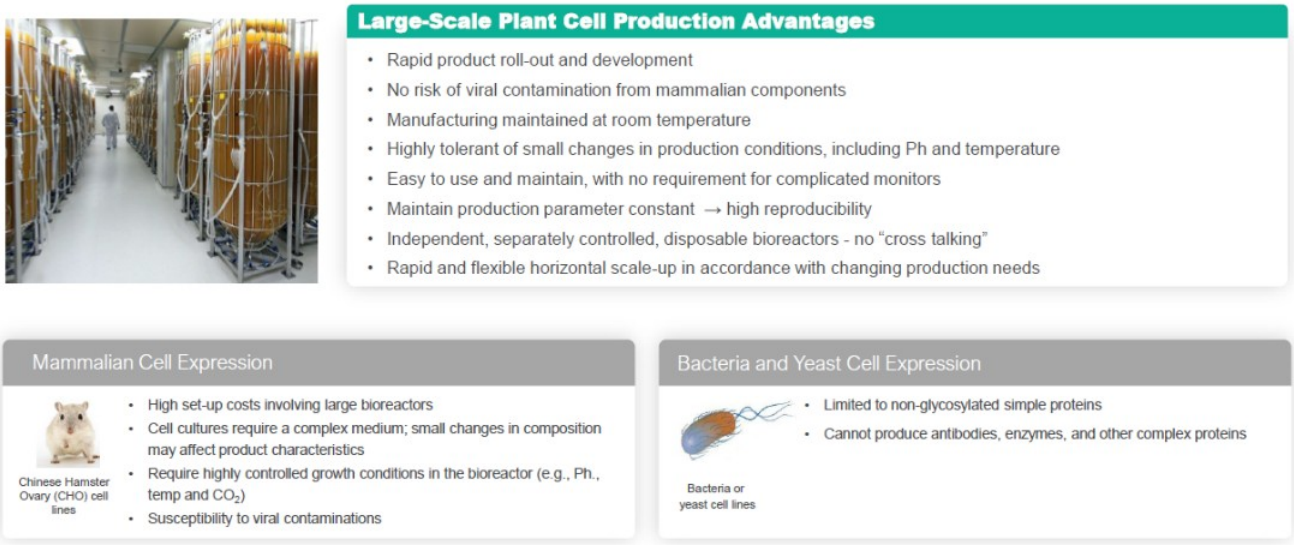
Our ProCellEx technology allows for many unique advantages, including: biologic optimization; an ability to handle complex protein expressions; flexible manufacturing with improvements through efficiencies, enhancements and/or rapid horizontal scale-ups; a simplified production process; elimination of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

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

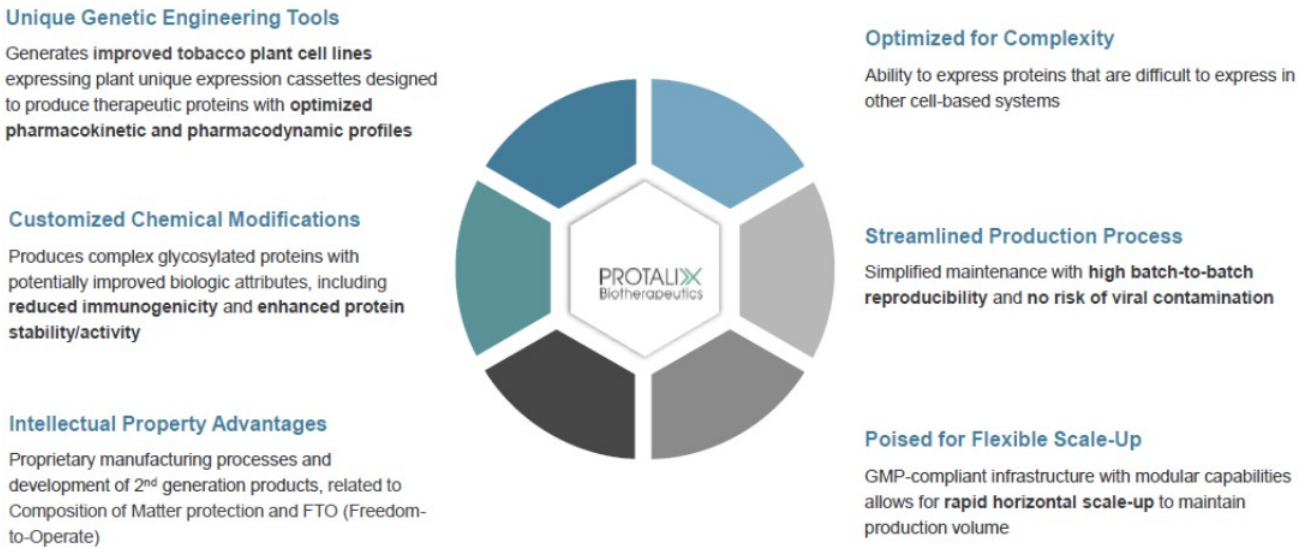
Our ProCellEx technology can be utilized to express complex therapeutic proteins belonging to different drug classes, such as enzymes, hormones, monoclonal antibodies, cytokines and vaccines. The entire protein expression process, from initial nucleotide cloning to large-scale production of the protein product, occurs under Current Good Manufacturing Practice-, or cGMP-, compliant, controlled processes. Our plant cell culture technology uses cells, such as carrot and tobacco (BY-2) cells, which undergo advanced genetic engineering and/or chemical modifications, and are grown on an industrial scale in a disposable, flexible bioreactor system. Our system does not involve mammalian or animal-derived components or transgenic field-grown or whole plants at any point in the production process.

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

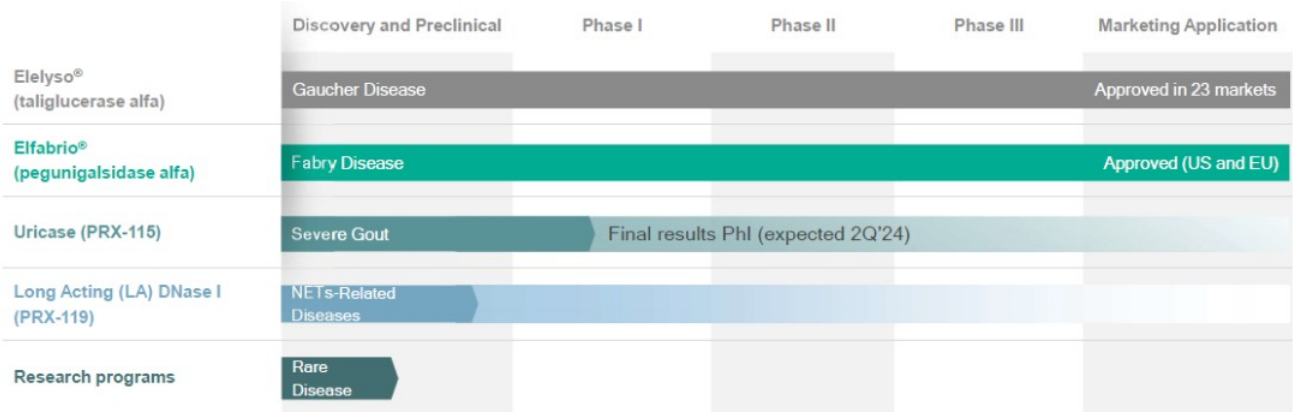
Plant Cell Production Advantages



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



Products and Product Pipeline



Our Marketed Products

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

Elelyso for the Treatment of Gaucher Disease

Elelyso (taliglucerase alfa), our first commercial product, was approved by the FDA in 2012 for injection as an ERT for the long-term treatment of adult patients with a confirmed diagnosis of type 1 Gaucher disease. In August 2014, the FDA approved Elelyso for injection for 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 23 markets including the United States, Brazil, Israel and others.

Gaucher disease, also known as glucocerebrosidase, or GCD, deficiency, is a rare genetic autosomal recessive disorder and one of the most common Lysosomal Storage Disorders, or LSDs, in the world. It is one of a group of disorders that affect specific enzymes that normally break down fatty substances for reuse in the cells. If the enzymes are missing or do not work properly, the substances can build up and become toxic. Gaucher disease occurs when a lipid called glucosylceramide accumulates in the cells of the bone marrow, lungs, spleen, liver, and sometimes the brain. Gaucher disease symptoms can include fatigue, anemia, easy bruising and bleeding,

severe bone pain and easily broken bones, and distended stomach due to an enlarged spleen and thrombocytopenia. Epidemiology of Gaucher disease varies; Recent literature provides that prevalence of Gaucher disease ranges from 0.70 to 1.75 per 100,000 in the general population. In people of Ashkenazi Jewish heritage, estimates of occurrence vary from approximately 1 in 400 to 1 in 850 people.

The global market for Gaucher disease, that includes Sanofi's Cerezyme®, Shire's Vpriv® and Sanofi's Cerdelga®, among others, was $1.6 billion in 2023, is forecasted to be approximately $1.6 billion in 2024 and is forecasted to grow at a CAGR of approximately 1% from 2023-2029.

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

Elfabrio for the Treatment of Fabry Disease

Elfabrio, our second commercial product, was approved by the EC for marketing in the EU and by the FDA for marketing in the United States in May 2023 for adult patients with Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage. 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. According to the EMA, overall, the benefit/risk balance of Elfabrio is positive in the claimed indication (Fabry disease). The FDA publicly released the internal review documents for Elfabrio. 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, our phase I\II clinical trial of Fabry disease, with confirmatory evidence provided by the *BALANCE* study. The FDA review team also concluded that the *BALANCE* study met its primary efficacy endpoint, which assessed the annualized rate of change in eGFR (estimated glomerular filtration rate) over 104 weeks. However, the FDA also determined that the results from the *BALANCE* study did not support a non-inferiority claim to the comparator product due to the lack of data to support the non-inferiority margin.

In August and September of 2023, Elfabrio was approved in Great Britain and Switzerland, respectively, and by the Israeli Ministry of Health in January 2024, for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease.

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

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

The global market for Fabry disease, that includes agalsidase beta, Sanofi's Fabrazyme®, agalsidase alfa, Shire's (acquired by Takeda Pharmaceutical Company Limited) Replagal® and Amicus Therapeutics' Galafold®, among others, is forecasted to be approximately $2.0 billion in 2023 and is forecasted to grow at a CAGR of 6.8% from 2023-2029 reaching approximately $3.1 billion in annual sales at the end of the decade.

Elfabrio Regulatory Background

On November 9, 2022, we, together with Chiesi, resubmitted to the FDA a BLA for PRX-102, the name we assigned to Elfabrio internally prior to its approvals, for the potential treatment of adult patients with Fabry disease. The initial BLA for PRX-102 was submitted to the FDA on May 27, 2020 under the FDA's Accelerated Approval pathway, and the submission was subsequently

accepted by the FDA and granted Priority Review designation. However, in April 2021, the FDA issued a complete response letter, or CRL, in response to the initial BLA. In preparation for the BLA resubmission, we and Chiesi participated in a Type A (End of Review) meeting with the FDA on September 9, 2021. As part of the meeting minutes provided by the FDA, which included the preliminary comments and meeting discussion, the FDA, in principle, agreed that the data package proposed to the FDA for a BLA resubmission had the potential to support a traditional approval of PRX-102 for the treatment of Fabry disease. The data package in the BLA resubmission, given the change in the regulatory landscape in the United States, included the final two-year analyses of our *BALANCE* study, which were completed in July 2022, and long-term data from our open-label extension study of PRX-102 in adult patients treated with a 2 mg/kg every four weeks dosage of PRX-102. The initial BLA included a comprehensive set of preclinical, clinical and manufacturing data compiled from our completed phase I/II clinical trial of PRX-102, including the related extension study, interim clinical data from our phase III BRIDGE clinical trial of PRX-102 for the treatment of Fabry disease, or the *BRIDGE* study, and safety data from our then on-going clinical studies of PRX-102 in adult patients receiving 1 mg/kg every two weeks.

No concerns relating to the potential safety or efficacy of PRX-102 in the submitted data package were raised in the CRL. The FDA noted in CRL that the FDA noted that an inspection of our manufacturing facility in Carmiel, Israel, including the FDA's subsequent assessment of any related FDA findings, is required before the FDA can approve a new drug. Due to travel restrictions during the COVID-19 pandemic, the FDA was unable to conduct the required pre-approval inspection during the review cycle. In addition to the foregoing, the FDA noted that agalsidase beta had recently been converted to full approval, a change in regulatory circumstances which had to be addressed in the resubmitted BLA for PRX-102.

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

On February 24, 2023, we, together with Chiesi, announced that the CHMP had adopted a positive opinion, recommending marketing authorization for PRX-102. The CHMP opinion was then referred for final action to the EC. As disclosed above, Elfabrio was subsequently approved by the EC for marketing in the EU and in the United States in May 2023 for adult patients with Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage.

Elfabrio Key Trials and Design

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

The phase III clinical program included three individual studies; the *BALANCE* study, the *BRIDGE* study the *BRIGHT* study, all of which have been completed. In the phase III clinical program overall, two potential dosing regimens for PRX-102 were analyzed; 1 mg/kg every two weeks, with the potential for improved efficacy and safety offering a potential alternative to existing enzyme replacement therapies, and 2 mg/kg every four weeks. The phase III program was preceded by the phase I/II clinical trial, a dose range finding study in ERT-naïve adult patients with Fabry disease, which was completed in 2016.

Phase III BALANCE Study

The *BALANCE* study (PB-102-F20, NCT02795676) was a pivotal 24-month, randomized, double blind, active control study of PRX-102 in adult Fabry patients with deteriorating renal function designed to evaluate the safety and efficacy of 1 mg/kg of PRX-102

administered every two weeks compared to agalsidase beta. The Clinical Study Report for the *BALANCE* study was completed in July 2022. The final analysis confirmed the positive top-line 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.

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.

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

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

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

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

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

Of the patients that completed the trial from both the PRX-102 and agalsidase beta treatment arms, 69 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 (PB-102-F30, NCT03018730) was a 12-month open-label, single arm switch-over study evaluating the safety and efficacy of PRX-102, 1 mg/kg infused every two weeks, in up to 22 Fabry patients previously treated with agalsidase alfa for at least two years and on a stable dose for at least six months. In the study, patients were screened and evaluated over three months while continuing agalsidase alfa treatment. The study was completed in December 2019.

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

PRX-102 was well-tolerated in the *BRIDGE* study, with all adverse events being transient in nature without sequelae. 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.

Of the patients that completed the trial, 18 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 is now sponsored by Chiesi.

Phase III BRIGHT Study

The *BRIGHT* study (PB-102-F50, NCT03180840) was a multicenter, multinational open-label, switch-over study designed to evaluate the safety, efficacy and pharmacokinetics of treatment with 2 mg/kg of PRX-102 administered every four weeks for 52 weeks (a total of 14 infusions). The study was completed in June 2020. The 2 mg/kg every four weeks dosage has not been approved by the EMA, FDA or any other jurisdiction.

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

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

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

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.

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

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

Of the patients that completed the trial, 29 opted, with the advice of the treating physician, to continue receiving PRX-102 2 mg/kg every four weeks in a long-term open-label extension study which is now sponsored by Chiesi. Two of such patients are being treated with 1 mg/kg every two weeks dosage.

Phase I/II Study

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

We initiated the phase I\II study after PRX-102, in preclinical studies, 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 ADAs.

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

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

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

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

Of the patients who completed the trial, 10 patients 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.

Extension Studies

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 initially opted, with the advice of the treating physician, to enroll in one of our long-term, open label, extension studies of PRX-102: 97 patients in the 1 mg/kg every two weeks extension study (PB-102-F60, NCT03566017) (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, NCT03614234). Two of the subjects in the PB-102-F51 study 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.

Over time, and as Elfabrio is approved for marketing in different jurisdictions, participants switch-out of the open-label extension studies. Most of them have transferred to a commercial setting; others withdraw for other reasons.

Pediatric FLY Study

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

Japanese RISE Study

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

Commercialization of Approved Products

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 as well as additional payments as consideration for drug product supply. The additional payments for drug product supplied are based on the average selling price of the drug product in the relevant territory multiplied by tiered payments, as detailed below. 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 for drug product purchased from Protalix based on the average selling price of the drug product in the relevant territory multiplied by 15% to 35%, depending on the amount of annual net sales outside of the United States.

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 for drug product purchased from

Protalix based on the average selling price of the drug product in the United States multiplied by 15% to 40%, subject to certain terms and conditions, depending on the amount of annual net sales in the United States.

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 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.

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.

Product Development Pipeline

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

PEGylated Uricase (PRX-115)

PRX-115 is our recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme under development for the potential treatment of patients with uncontrolled gout. The uricase enzyme converts uric acid to allantoin, which is easily eliminated through urine and does not exist naturally in humans. This recombinant enzyme, expressed via our ProCellEx system, is designed to lower uric acid levels and improve clinical manifestation of the disease while having low immunogenicity and increased half-life of the drug in the blood. Pre-clinical data demonstrates long half-life, reduced immunogenic risk and high specific activity which supports the potential of PRX-115 to be a safe and effective treatment for patients with gout. One-month multiple dosing toxicity studies in two species and 6-month multiple dosing toxicity study in one species were conducted to support single and multiple dose studies is humans.

PRX-115 is being analyzed for the potential treatment of uncontrolled gout in our phase I clinical trial of PRX-115 for the potential treatment of uncontrolled gout entitled “A Double-blind, Placebo-controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Properties of PRX-115 in Adult Volunteers With Elevated Uric Acid Levels” (NCT05745727), or the *FIH* Study. The first subject was dosed in the study on March 21, 2023. 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. The study was initially designed to include sequential dosing cohorts, each composed of eight subjects (six active and two placebo), a 3:1 ratio. Subjects in each cohort, males and females aged 18 through 65, received a single dose of PRX-115 and are analyzed for safety, pharmacokinetics (PK) and pharmacodynamics (PD) (concentrations of plasma uric acid) for 85 days. As of March 31, 2024, 56 subjects with no previous exposure to PEGylated uricase have been enrolled in the study.

After a review of initial positive top-line results from the seven cohorts, and following the review and acceptance of the safety data from cohort 7 by the safety and monitoring committee for dose escalation for the FIH Study, the Company decided to expand the study by adding an eighth cohort of eight new subjects to analyze a higher dose and its potential to result in increased exposure time. In addition to the expansion of the FIH Study, the Company also decided to commence preparations for a phase II clinical trial of PRX-115.

Key preliminary results from the FIH Study are as follows:

- Exposure to PRX-115 increased in a dose-dependent manner.

- PRX-115 rapidly reduced plasma uric acid concentrations to below 6.0 mg/dL over time following a single administration. The effect of PRX-115 on plasma uric acid concentrations and the duration of response was found to be dose dependent.

- PRX-115 was well-tolerated. Twenty-six percent (11/42) of the subjects treated with PRX-115 in the first seven cohorts reported study drug-related adverse events, the majority being mild to moderate and transient in nature. One subject in cohort 2 experienced an anaphylactic reaction immediately following the commencement of the infusion, and the reaction was fully resolved. There were no other serious adverse events reported in the study, and no adverse events were reported in the highest doses, cohorts 6 and 7.

Gout is the most common inflammatory arthritis, affecting an estimated 14.0 million adults in the United States, 2.0 million in France, 2.0 million in United Kingdom, 0.7 million in Italy, 1.5 million in Germany, 0.7 million in Spain and over 190.0 million in China. An estimated approximately 5% of the gout population is considered to have chronic refractory disease. The risk of gout increases with age, and it is thus more common in ageing populations. Gout results from sustained elevation of serum urate levels (hyperuricaemia). Urate levels may increase due to diet, genetic predisposition and environmental factors leading to the deposition of monosodium urate crystals and\or tophi in joints, tendons and other tissues, which triggers recurrent episodes of pronounced acute inflammation, known as gout flares. Gout leads to substantial morbidity, severe pain, reduced quality of life, decreased physical function, increased healthcare costs, and lost economic productivity. Furthermore, gout is strongly associated with a number of comorbidities, including hypertension, cardiovascular disease, renal impairment, diabetes, obesity, hyperlipidaemia and frequently in a combination known as the metabolic syndrome.

Uncontrolled gout occurs when oral gout therapies fail to lower serum uric acid (sUA) levels below the gout guideline goal of 6 mg/dL at the maximum medically appropriate dosage or when gout does not improve clinically with oral urate-lowering therapies (ULTs), and may involve systemic urate deposition. Uncontrolled gout is also reported to involve urate crystal deposition and associated inflammation in joints, soft tissues, and organs, such as the heart, kidneys, and eyes. Currently available ULTs can be effective in treating gout. However, low adherence, under dosing and disease progression that cause high patient burden require new, effective and safe therapies to treat these underserved uncontrolled gout patients.

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

PRX-119

PRX-119 is our plant cell-expressed PEGylated recombinant human DNase I product candidate 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 these conditions.

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

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 March 31, 2024, we hold a broad portfolio of more than 70 patents in Europe, the United States, Israel and additional countries worldwide, as well as more than 45 pending patent applications.

Research & Development

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

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

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, 2023.

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

Results of Operations

Three months ended March 31, 2024 compared to the three months ended March 31, 2023

Revenues from Selling Goods

We recorded revenues from selling goods of $3.7 million during the three months ended March 31, 2024, a decrease of $1.4 million, or 27%, compared to revenues of $5.1 million for the three months ended March 31, 2023. The decrease resulted primarily from a decrease of $1.1 million in sales to Pfizer, and of $0.3 million in sales to Brazil which decreases resulted primarily from the timing of delivery.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $0.1 million for the three months ended March 31, 2024, a decrease of $4.4 million, or 98%, compared to revenues of $4.5 million for the three months ended March 31, 2023. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. The decrease resulted primarily from the completion of our research and development obligations with respect to Elfabrio and, as Elfabrio was approved in

the United States and the European Union in May 2023, from the completion of the regulatory processes related to the review of the BLA and the MAA for Elfabrio by the FDA and EMA, respectively.

Cost of Goods Sold

Cost of goods sold was $2.6 million for the three months ended March 31, 2024, a decrease of $0.5 million, or 16%, from cost of goods sold of $3.1 million for the three months ended March 31, 2023. The decrease in cost of goods sold was primarily the result of the decrease in sales to Pfizer and to Brazil.

Research and Development Expenses

For the three months ended March 31, 2024, our total research and development expenses were approximately $2.9 million comprised of approximately $0.5 million in subcontractor-related expenses, approximately $1.5 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.7 million of other expenses. For the three months ended March 31, 2023, our total research and development expenses were approximately $5.8 million comprised of approximately $3.5 million of subcontractor-related expenses, approximately $1.5 million of salary and related expenses, approximately $0.1 million of materials-related expenses and approximately $0.7 million of other expenses.

Total decrease in research and developments expenses for the three months ended March 31, 2024 was $2.9 million, or 50%, compared to the three months ended March 31, 2023. 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 to continue to incur significant, increasing research and development expenses as we enter into a more advanced stage of preclinical and clinical trials for certain of our product candidates.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $3.1 million for the three months ended March 31, 2024 and for the three months ended March 31, 2023.

Financial Income, Net

Financial income, net were $0.1 million for the three months ended March 31, 2024, compared to financial expenses, net of $0.5 million for the three months ended March 31, 2023. The change resulted primarily from higher interest income on bank deposits and lower notes interest expenses due to notes conversions executed in 2023.

Income taxes

In the three months ended March 31, 2024, we recorded a tax benefit of approximately $(0.1) million, compared to income taxes of $0.2 million for the three months ended March 31, 2023. Income taxes recorded are primarily the result of the provision for current taxes in respect of Section 174 of the TCJA.

Liquidity and Capital Resources

Our sources of liquidity include our cash and cash equivalents balances and short term bank deposits. At March 31, 2024, we had $48.5 million in cash and cash equivalents and short term bank deposits. We have primarily financed our operations through equity and debt financings, business collaborations, grants funding and revenues from selling goods.

During the year ended December 31, 2023, we raised gross proceeds equal to approximately $24.9 million from the sale of 12,560,150 shares of our common stock under our ATM program. All such sales were completed during the quarters ended March 31, 2023 and June 30, 2023. No sales were completed during the quarters ended September 30, 2023, December 31, 2023 or March 31, 2024.

On August 25, 2021, we completed exchanges, or the Exchanges, with institutional note holders of a substantial majority of the then outstanding 7.50% Senior Secured Convertible Notes due 2021, or the 2021 Notes. The Exchanges involved the exchange of an aggregate of $54.65 million principal amount of 2021 Notes for an aggregate of $28.75 million principal amount of newly issued 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 of the 2024 Notes is 563.2216 shares of our common stock per $1,000 principal amount of 2024 Notes, which is equivalent to an initial conversion price of approximately $1.7755 per share of common stock, subject to adjustment

in certain circumstances. This initial conversion price represents a premium of approximately 32.5% relative to the closing price of the common stock on the NYSE American on August 13, 2021. After giving effect to the Exchanges, $3.27 million aggregate principal amount of the 2021 Notes remained outstanding. On November 15, 2021, all of the then outstanding 2021 Notes matured and were paid in full.

The 2024 Notes were issued pursuant to the 2024 Indenture which was entered into 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. Interest on the 2024 Notes are payable semi-annually at a rate of 7.50% per annum. The 2024 Notes will mature three years after the issuance thereof, unless earlier purchased, converted, exchanged or redeemed and will be guaranteed by our subsidiaries. The 2024 Notes are secured by perfected liens on all of our assets, including those of our subsidiaries.

We believe that our cash, cash equivalents and short term bank deposits as of March 31, 2024 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 provided by operations was $4.2 million for the three months ended March 31, 2024. The net loss for the three months ended March 31, 2024 of $4.6 million was increased by a $3.3 million increase in inventories, a $1.4 million decrease in accounts payable and accruals and was offset by an $11.0 million increase in contracts liability, a $1.7 million decrease in accounts receivable-trade and other assets and $1.0 million in share-based compensation. Net cash used in investing activities for the three months ended March 31, 2024 was $0.6 million and consisted primarily of the purchase of property and equipment.

Net cash used in operations was $3.0 million for the three months ended March 31, 2023. The net loss for the three months ended March 31, 2023 of $3.1 million was increased by a $1.4 million decrease in contracts liability and a $3.5 million increase in inventories and was partially offset by a $3.8 million decrease in accounts receivable-trade and other assets and $0.5 million in share-based compensation. Net cash provided by investing activities for the three months ended March 31, 2023 was $4.7 million and consisted primarily of proceeds from sale of short-term deposits. Net cash provided by financing activities was $14.2 million resulting primarily from the sale of common stock under our ATM program.

As of March 31, 2024, the total principal amount of our 2024 Notes outstanding was $20.42 million, and 2020 Warrants to purchase 13,439,712 shares were outstanding.

Future Funding Requirements

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

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 March 31, 2024, we were in compliance with all covenants.

As we increase our research and developments efforts with respect to our current and future product candidates, we expect to continue to incur significant expenditures. We cannot anticipate the costs or the timing of the occurrence of such costs. Although we expect the revenues generated from the sales of Elfabrio and Elelyso will increase, such revenues may not be sufficient to fund the expenditures. To the extent we need to obtain additional financing in excess of such anticipated revenues, it may be difficult for us to do so given the volatility of the price of our common stock. Our material cash needs for the next 24 months will include, among other expenses, (i) costs of preclinical and clinical trials, (ii) employee salaries, (iii) payments for rent and operation of our manufacturing facilities, (iv) fees to our consultants and legal advisors, patent advisors and fees for service providers in connection with our research and development efforts, (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 Elfabrio and Elelyso, corporate collaborations, licensing or similar arrangements, public or private equity offerings and/or debt financings. We currently do not have any commitments for future external funding, except with respect to the milestone payments that may become payable under the Chiesi Agreements. On February 27, 2023, we entered into the 2023 Sales Agreement pursuant to which we may sell from time to time through the Agent ATM Shares having an aggregate offering price of up to $20.0 million as we had then completed the ATM program under the 2021 Sales Agreement. As of March 31, 2024, shares of our common stock for total gross proceeds of approximately $6.4 million remain available to be sold under the 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 nine months ended of March 31, 2024.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of March 31, 2024 and December 31, 2023.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Currency Exchange Risk

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

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

	Three Months Ended March 31,		December 31,
	2024	2023	2023
Average rate for period	3.662	3.536	3.687
Rate at period-end	3.681	3.615	3.627

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 March 31, 2024 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, 2023.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

During the quarter ended March 31, 2024, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 6. Exhibits

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	10-Q	001-33357	3.6	August 7, 2023	
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	10-Q	001-33357	10.1	August 7, 2023	
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: May 10, 2024

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

Date: May 10, 2024

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

EXHIBIT 31.1

CERTIFICATION

I, Dror Bashan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2024

/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: May 10, 2024

/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 March 31, 2024 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: May 10, 2024

/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 March 31, 2024 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: May 10, 2024

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