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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2025

OR

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

For the transition period from _____ to_____

001-33357
(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

On August 1, 2025, approximately 79,732,115 shares of the Registrant's common stock, $0.001 par value, were outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,895	$ 19,760
Short-term bank deposits	15,503	15,070
Accounts receivable – Trade	9,443	2,909
Other assets	1,513	1,096
Inventories	21,131	21,243
Total current assets	$ 65,485	$ 60,078
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 520	$ 462
Property and equipment, net	4,746	4,591
Deferred income tax asset	2,738	2,856
Operating lease right of use assets	4,997	5,430
Total assets	$ 78,486	$ 73,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,689	$ 4,533
Other	15,930	19,588
Operating lease liabilities	1,472	1,500
Total current liabilities	$ 24,091	$ 25,621
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 615	$ 559
Operating lease liabilities	3,877	4,026
Total long term liabilities	$ 4,492	$ 4,585
Total liabilities	$ 28,583	$ 30,206
COMMITMENTS		
STOCKHOLDERS' EQUITY	49,903	43,211
Total liabilities and stockholders' equity	$ 78,486	$ 73,417

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

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

	Six Months Ended		Three Months Ended	
	June 30, 2025	June 30, 2024	June 30, 2025	June 30, 2024
REVENUES FROM SELLING GOODS	$ 25,435	$ 16,981	$ 15,440	$ 13,304
REVENUES FROM LICENSE AND R&D SERVICES	336	241	218	170
TOTAL REVENUE	25,771	17,222	15,658	13,474
COST OF GOODS SOLD	(14,050)	(12,058)	(5,870)	(9,456)
RESEARCH AND DEVELOPMENT EXPENSES	(9,467)	(5,848)	(5,992)	(2,961)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(5,227)	(6,599)	(2,624)	(3,484)
OPERATING INCOME (LOSS)	(2,973)	(7,283)	1,172	(2,427)
FINANCIAL EXPENSES	(628)	(757)	(783)	(367)
FINANCIAL INCOME	530	1,035	272	522
FINANCIAL INCOME (EXPENSES), NET	(98)	278	(511)	155
INCOME (LOSS) BEFORE TAXES ON INCOME	(3,071)	(7,005)	661	(2,272)
TAXES ON INCOME (TAX BENEFIT)	384	(207)	497	(69)
NET INCOME (LOSS)	$ (3,455)	$ (6,798)	$ 164	$ (2,203)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ (0.04)	$ (0.09)	$ 0.00	$ (0.03)
DILUTED	$ (0.04)	$ (0.09)	$ 0.00	$ (0.03)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	77,651,330	73,172,980	78,663,884	73,308,281
DILUTED	77,651,330	73,172,980	81,271,610	73,308,281

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

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

	Common Stock (1)	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
Balance at January 1, 2024	**72,952,124**	**$ 73**	**$ 415,045**	**$ (381,549)**	**$ 33,569**
Changes during the six-month period ended June 30, 2024:					
Initial adoption of ASU 2020-06			(393)	224	(169)
Share-based compensation related to stock options			833		833
Share-based compensation related to restricted stock awards	340,550	*	1,146		1,146
Net loss for the period				(6,798)	(6,798)
Balance at June 30, 2024	**73,292,674**	**$ 73**	**$ 416,631**	**$ (388,123)**	**$ 28,581**
Balance at January 1, 2025	**75,850,275**	**$ 76**	**$ 421,528**	**$ (378,393)**	**$ 43,211**
Changes during the six-month period ended June 30, 2025:					
Issuance of common stock under the Sales Agreement, net	2,775,215	3	6,809		6,812
Share-based compensation related to stock options			599		599
Share-based compensation related to restricted stock awards			368		368
Exercise of warrants and options	1,106,625	1	2,367		2,368
Net loss for the period				(3,455)	(3,455)
Balance at June 30, 2025	**79,732,115**	**$ 80**	**$ 431,671**	**$ (381,848)**	**$ 49,903**
Balance at March 31, 2024	**73,052,124**	**$ 73**	**$ 415,633**	**$ (385,920)**	**$ 29,786**
Changes during the three-month period ended June 30, 2024:					
Share-based compensation related to stock options			333		333
Share-based compensation related to restricted stock awards	240,550	*	665		665
Net loss for the period				(2,203)	(2,203)
Balance at June 30, 2024	**73,292,674**	**$ 73**	**$ 416,631**	**$ (388,123)**	**$ 28,581**
Balance at March 31, 2025	**78,133,829**	**$ 78**	**$ 427,142**	**$ (382,012)**	**$ 45,208**
Changes during the three-month period ended June 30, 2025:					
Issuance of common stock under the Sales Agreement, net	1,450,036	2	3,949		3,951
Share-based compensation related to stock options			263		263
Share-based compensation related to restricted stock awards			164		164
Exercise of warrants and options	148,250	*	153		153
Net income for the period				164	164
Balance at June 30, 2025	**79,732,115**	**$ 80**	**$ 431,671**	**$ (381,848)**	**$ 49,903**

*Represents an amount equal to less than $1.

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

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

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

	Six Months Ended	
	June 30, 2025	June 30, 2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (3,455)	$ (6,798)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation	967	1,979
Depreciation	706	641
Financial expenses (income), net	108	(975)
Changes in accrued liability for employee rights upon retirement	10	16
Changes in deferred income tax asset	118	(207)
Gain on amounts funded in respect of employee rights upon retirement	(6)	(10)
Changes in operating assets and liabilities:		
Increase in contracts liability	—	12,695
Increase in accounts receivable-trade and other assets	(6,919)	(5,308)
Changes in operating lease right of use assets, net	(38)	20
Decrease (increase) in inventories	112	(1,674)
Increase (decrease) in accounts payable and accruals	(1,894)	199
Net cash provided by (used in) operating activities	$ (10,291)	$ 578
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	$ (737)	$ (770)
Amounts funded in respect of employee rights upon retirement, net	(13)	(16)
Net cash used in investing activities	$ (750)	$ (786)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock under the Sales Agreement, net	$ 6,812	$ —
Exercise of warrants and options	2,368	—
Net cash provided by financing activities	$ 9,180	$ —
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ (4)	$ (27)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,865)	(235)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	19,760	23,634
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 17,895	$ 23,399

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

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

	Six Months Ended	
	June 30, 2025	June 30, 2024
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 378	$ 121
Operating lease right of use assets obtained in exchange for new operating lease liabilities	$ 33	$ 258
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Interest paid	$ -	$ 766
Interest received	$ 220	$ 56

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

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

NOTE 1 - SIGNIFICANT ACCOUNTING POLICIES

a. General

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

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

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

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

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

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

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

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

The Company has licensed the rights to commercialize Elelyso worldwide (other than Brazil) to Pfizer Inc. ("Pfizer"), and in Brazil to Fundação Oswaldo Cruz ("Fiocruz"), an arm of the Brazilian Ministry of Health (the "Brazilian MoH"). Elelyso is marketed as BioManguinhos alfataliglicerase in Brazil. The Company has partnered with Chiesi Farmaceutici S.p.A. ("Chiesi") for the development and commercialization of Elfabrio through two exclusive global licensing and supply agreements. On October 19, 2017, Protalix Ltd., 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.

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

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

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

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

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

Because the Company's operations are conducted in the State of Israel, the business and operations may be directly affected by economic, political, geopolitical and military conditions in Israel. In October 2023 Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and attacked civilian and military targets. The infiltration was accompanied by extensive rocket attacks by Hamas on industrial, civilian and military targets throughout Israel. At the same time, clashes between Israel and Hezbollah in Lebanon increased. In response, Israel's security cabinet declared war against Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Since the outbreak of the war, other regional actors, including Iran, have taken military action against Israel, as discussed above. In June 2025, Israel launched significant aerial attacks on military and related sites in Iran, and the Iranian military responded with missile and drone attacks in Israel, which was followed by strategic bombing by the U.S. Air Force. The U.S. action was followed by a cease fire with Iran which remains in effect as of the date hereof. Although ceasefire negotiations are on-going with Hamas and the level of military activity has decreased in recent months compared to previous levels, 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 Company's facilities are recognized as an "essential enterprise" in Israel which means the Company operates or can be operated for the purposes of state defense or public security or for the maintenance of essential supplies or services, allowing the Company to maintain operations during emergencies. However, the situation 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 its product candidates. The Company believes that its cash and cash equivalents and short-term bank deposits as of June 30, 2025, are sufficient to satisfy the Company's capital needs for at least 12 months from the date that these financial statements are issued.

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

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

c. Net earnings (loss) per share

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

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

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

d. Convertible notes

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

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

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

e. New accounting pronouncements

Recently issued accounting pronouncements, not yet adopted

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

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

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

NOTE 2 - INVENTORIES

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

(*U.S. dollars in thousands*)	June 30, 2025	December 31, 2024
Raw materials	$ 4,357	$ 4,549
Work in progress	8,144	11,245
Finished goods	8,630	5,449
Total inventory	$ 21,131	$ 21,243

NOTE 3 – FAIR VALUE MEASUREMENT

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

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

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

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

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

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

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

NOTE 4 – STOCK TRANSACTIONS

a. During the three months ended March 31, 2025, the Company issued 908,000 shares of Common Stock in connection with the exercise of warrants issued in 2020 generating proceeds equal to approximately $2.1 million from such exercises. The remaining warrants expired on March 11, 2025. Accordingly, as of March 12, 2025, no warrants remained outstanding.

b. During the six months ended June 30, 2025, the Company sold, in the aggregate, 2,775,215 shares of Common Stock under the Sales Agreement. The Company generated gross proceeds equal to approximately $7.0 million in connection with such sales (issuance costs were $0.2 million).

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

c. During the six months ended June 30, 2025, the Company issued, in the aggregate, 198,625 shares of Common Stock in connection with the exercise of options to purchase 198,625 shares of Common Stock by certain current and former employees of the Company. The Company received cash proceeds equal to $0.3 million in connection with such exercises.

NOTE 5 – EARNINGS (LOSS) PER SHARE

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

(In thousands, except share data)	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024
Numerator:				
Net income (loss) for basic and diluted calculation	$ (3,455)	$ (6,798)	$ 164	$ (2,203)
Denominator:				
Weighted average shares of Common Stock outstanding for basic calculation	77,651,330	73,172,980	78,663,884	73,308,281
Weighted average dilutive effect of stock options and restricted stock			2,607,726	
Weighted average shares of Common Stock outstanding for diluted calculation	77,651,330	73,172,980	81,271,610	73,308,281

Diluted earnings (loss) per share do not include 12,936,429 shares of Common Stock underlying outstanding stock options, unvested shares of restricted stock and warrants for the six months ended June 30, 2025 because the effect would be anti-dilutive.

Diluted earnings (loss) per share do not include 2,365,709 shares of Common Stock underlying outstanding stock options for the three months ended June 30, 2025 because the effect would be anti-dilutive.

Diluted earnings (loss) per share do not include 31,744,960 and 31,791,645 shares of Common Stock underlying outstanding stock options, unvested shares of restricted stock, warrants and the 2024 Notes for the three and six months ended June 30, 2024, respectively, because the effect would be anti-dilutive.

NOTE 6 – TAXES ON INCOME (TAX BENEFIT)

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

(U.S. dollars in thousands)	Six Months Ended June 30, 2025	Six Months Ended June 30, 2024	Three Months Ended June 30, 2025	Three Months Ended June 30, 2024
Current taxes on income	$ 266	$ -	$ 266	$ -
Deferred taxes on income	118	(207)	$ 231	$ (69)
Total taxes on income (tax benefit)	$ 384	$ (207)	$ 497	$ (69)

The Company had an effective tax rate of 13% for the six months ended June 30, 2025 compared to an effective tax rate of (3)% for the six months ended June 30, 2024. For the six months ended June 30, 2025, the difference between the Company's effective tax rate and the U.S. federal statutory rate of 21% was the result of forecasted profits derived primarily from U.S. taxable GILTI income mainly due to Section 174 of the U.S. Tax Cuts and Jobs Act of 2017 (the "TCJA"), which was enacted in December 2017.

On July 4, 2025, tax reform legislation was enacted in the United States through the passage of H.R.1, One Big Beautiful Bill Act ("HR1"), which includes significant corporate tax changes, including a restoration of the current deductibility for domestic research expenditures beginning in 2025, with transition options for previously capitalized amounts. The Company continues to evaluate the impact that the new legislation will have on the consolidated financial statements.

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

NOTE 7 – SEGMENT INFORMATION

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

b. Segment information:

	Six Months Ended June 30,		Three Months Ended June 30,	
(U.S. dollars in thousands)	2025	2024	2025	2024
Revenues from customers	$ 25,771	$ 17,222	$ 15,658	$ 13,474
Less:				
Employee salaries and related expenses	10,649	10,357	5,444	5,213
Sub-contractors expense	7,463	4,764	4,773	2,609
Interest expense	—	761	—	379
Interest income	(528)	(757)	(272)	(374)
Depreciation	706	641	360	319
Other segment expenses*	10,552	8,461	4,692	7,600
Income (loss) before taxes on income	(3,071)	(7,005)	661	(2,272)
Taxes on income (tax benefit)	384	(207)	497	(69)
Segment net income (loss)	$ (3,455)	$ (6,798)	$ 164	$ (2,203)

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

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

	Six Months Ended June 30,		Three Months Ended June 30,	
(U.S. dollars in thousands)	2025	2024	2025	2024
Gaucher disease:				
Pfizer (Ireland)	$ 12,626	$ 8,001	$ 5,647	$ 6,874
Fiocruz (Brazil)	$ 3,016	$ 7,266	$ -	$ 4,716
Fabry disease:				
Chiesi (Italy)	$ 9,793	$ 1,714	$ 9,793	$ 1,714
Total revenues from selling goods	$ 25,435	$ 16,981	$ 15,440	$ 13,304
Revenues from license and R&D services	$ 336	$ 241	$ 218	$ 170

d. Long lived assets are located in Israel.

NOTE 8 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

Balance sheets:

	June 30,	December 31,
(U.S. dollars in thousands)	2025	2024
Accounts payable and accruals – other:		
Payroll and related expenses	$ 1,527	$ 1,343
Provision for vacation	2,209	1,811
Accrued expenses	7,311	9,568
Royalties payable	763	1,080
Income tax payable	3,742	3,476
Payable to customer	-	2,056
Property and equipment suppliers	378	254
	$ 15,930	$ 19,588

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

NOTE 9 – SUBSEQUENT EVENTS

Since the end of the quarter ended June 30, 2025, the Company collected approximately $1.4 million from sales to Pfizer and approximately $7.8 million from sales to Chiesi.

On July 20, 2025, the Company granted, with the approval of the Company's compensation committee, 10-year options to purchase 597,990 shares of Common Stock, in the aggregate, to the Company's incoming Sr. Vice President and Chief Financial Officer under the under the Company's Amended and Restated 2006 Employee Stock Incentive Plan, as amended (the "Plan"). The options have an exercise price equal to $1.45 per share and vest over a three-year period in 12 equal quarterly increments. Vesting of the options is subject to automatic acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan, and are subject to certain other terms and conditions. The Company estimated the aggregate fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $0.6 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, 2024. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements within the meanings of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and words or phrases of similar import, as they relate to our company, our subsidiary or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements as a result of several factors, including those set forth in this Quarterly Report on Form 10-Q.

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

- risks related to the commercialization of Elfabrio® (pegunigalsidase alfa-iwxj), our approved product for the treatment of adult patients with Fabry disease;
- risks relating to Elfabrio's market acceptance, competition, reimbursement and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product;
- the possible disruption of our operations due to 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 of our products and product candidates;
- failure or delay in the commencement or completion of our preclinical studies and clinical trials, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; inability to monitor patients adequately during or after treatment; and/or lack of sufficient funding to finance our clinical trials;
- delays in the approval or potential rejection of any applications we file with the FDA, European Medicines Agency, or EMA, or other health regulatory authorities for our other product candidates, and other risks relating to the review process;
- risks associated with global conditions and developments such as new or increased tariffs, new trade restrictions, supply chain challenges, the inflationary environment and tight labor market, and instability in the banking industry, which may adversely impact our business, operations and ability to raise additional financing if and as required and on terms acceptable to us;
- risks related to any transactions we may effect in the public or private equity or debt markets to raise capital to finance future research and development activities, general and administrative expenses and working capital;
- risks relating to our evaluation and pursuit of strategic partnerships;

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

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

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

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

- risks relating to the compliance Fiocruz with its purchase obligations under the Brazil 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

- On June 30, 2025, we announced that we had been added to the Russell 3000® and Russell 2000® Indexes, effective as of the U.S. market close on June 27, 2025, as part of the 2025 Russell indexes annual reconstitution.

- On July 21, 2025, we announced the appointment of Gilad Mamlok as our new Senior Vice President and Chief Financial Officer, effective August 24, 2025, succeeding Eyal Rubin. To ensure a seamless transition, Mr. Mamlok has joined the company and is working alongside Mr. Rubin. After his tenure as Chief Financial Officer ends, Mr. Rubin will continue to be available to as necessary until October 2025.

Our Business

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

To date, we have successfully developed two commercial products, both of which are enzyme replacement therapies (ERTs): Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease and Elelyso® (taliglucerase alfa) for the treatment of adult patients and children four years of age and greater with Gaucher disease. Elelyso was first

approved by the FDA in May 2012 and is now approved for marketing in 23 markets including Brazil, Israel and others. Elfabrio, which we referred to as PRX-102 during its development stage, has been approved for marketing in the United States, the European Union, Great Britain, Switzerland, Peru, Israel, Russia, Singapore Australia and Taiwan. We have licensed the rights to commercialize Elelyso worldwide (other than Brazil) to Pfizer, and in Brazil to Fiocruz. Elelyso is marketed as BioManguinhos alfataliglicerase in Brazil. We have partnered with Chiesi for the development and commercialization of Elfabrio.

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

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

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

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

In addition to Elelyso and Elfabrio, we are developing PEGylated uricase, or PRX-115, for the treatment of uncontrolled gout, Long Acting (LA) DNase I, or PRX-119, for the treatment of NETs-related diseases, and a number of other technologies and preclinical assets. We have completed a phase I First-in-Human clinical trial of PRX-115 and we are currently in the advance stages of preparations for a phase II clinical trial of PRX-115 which we expect to commence in the second half of 2025.

Product Pipeline

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

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

ProCellEx: Our Proprietary Protein Expression System

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

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

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

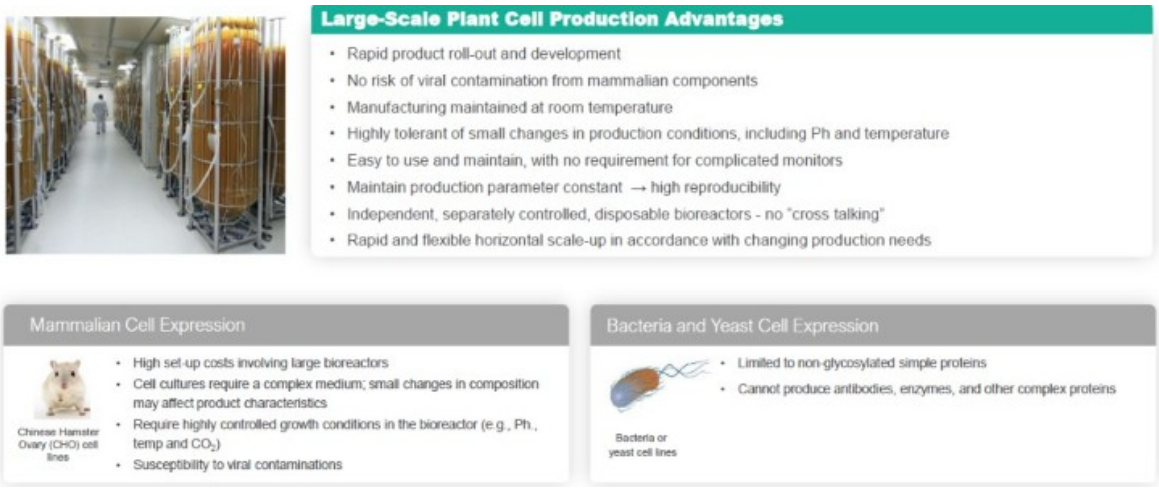
We developed ProCellEx based on our plant cell culture technology for the development, expression and manufacture of recombinant proteins that are the essential foundation of modern biotechnology. We develop new, recombinant therapeutic proteins by using the natural capability of agrobacterium to transfer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

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

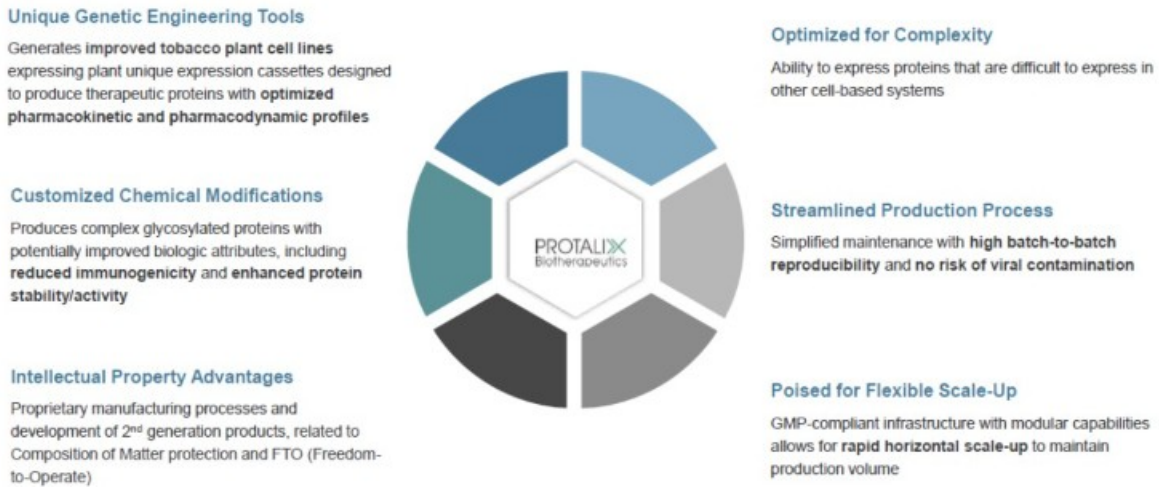
Cell growth, from initiating scale-up steps from a cell-bank through large-scale production takes place in a clean-room environment in flexible, sterile, custom-designed polyethylene bioreactors, and does not require the use of large stainless-steel bioreactors commonly used in mammalian-based systems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

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

Plant Cell Production Advantages



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



Our Marketed Products

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

Elelyso for the Treatment of Gaucher Disease

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

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

The global market for Gaucher disease, that includes Sanofi's Cerezyme®, Shire's (acquired by Takeda Pharmaceutical Company Limited) Vpriv® and Sanofi's Cerdelga®, among others, was $1.7 billion in 2024, is forecasted to be approximately $1.7 billion in 2025 and is forecasted to grow at a compound annual growth rate (CAGR) of approximately -1.66% from 2024-2030.

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

Elfabrio for the Treatment of Fabry Disease

Elfabrio, our second commercial product, was approved by the EC for marketing in the EU and by the FDA for marketing in the United States in May 2023 for adult patients with Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage. According to the EMA, overall, the benefit/risk balance of Elfabrio is positive in the claimed indication (Fabry disease). Similarly, the FDA review team concluded that in the context of Fabry disease as a rare, serious disease with limited therapeutic options that may not be suitable to all individual patients, the benefit-risk of Elfabrio is favorable for the treatment of adults with confirmed Fabry disease. The FDA noted its determination that substantial evidence of effectiveness for Elfabrio in Fabry patients was established with one adequate and well-controlled study, our phase 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.

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

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

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

The global market for Fabry disease, that includes agalsidase beta, Sanofi's Fabrazyme®, agalsidase alfa, Shire's Replagal® and Amicus Therapeutics' Galafold®, among others, is forecasted to be approximately $2.3 billion in 2025 and is forecasted to grow at a CAGR of 7.39% from 2024-2030 reaching approximately $3.2 billion in annual sales in 2030.

Regulatory Background of Elfabrio

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

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

In December 2024, the EMA validated Chiesi's Variation Submission for PRX-102. The Variation Submission seeks to add an additional dose and dosing regimen, 2 mg/kg body weight administered every four weeks in adult patients with Fabry disease, to the current Elfabrio label.

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 and the *BRIGHT* study. 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.

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, completed in July 2022, demonstrated a favorable tolerability profile. A total of 78 patients who were previously treated with agalsidase beta for at least one year with an eGFR slope at screening worse than -2 mL/min/1.73 m^2/year were enrolled in the study. Patients were randomized on a 2:1 ratio for switching to PRX-102 or continuing on agalsidase beta. A total of 77 patients were treated; 52 with PRX-102 and 25 with agalsidase beta. Approximately 40% of the enrolled patients were female.

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

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.

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

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

Phase 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 2 mg/kg every four weeks dosage has not been approved by the EMA, FDA or any other jurisdiction.

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

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

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

Overall, 33 of 183 total TEAEs reported in nine (30.0%) of the patients were considered treatment related; all were mild or moderate in severity and the majority were resolved at the end of the study. There were no serious or severe treatment-related TEAEs and no TEAEs led to death or study withdrawal. Of the treatment-related TEAEs, 27 were infusion-related reactions (IRRs) and the remainder were single events of diarrhea, erythema, fatigue, influenza-like illness, increases urine protein/creatinine ratio, and urine positive for

white blood cells. The 27 IRRs were reported in five (16.7%) patients, all male. All IRRs occurred during the infusion or within two hours post-infusion; no events were recorded between two and 24 hours post-infusion.

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

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

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

Phase 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.

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

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

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

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

Extension Studies

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

the 2 mg/kg every four weeks extension study (PB-102-F51, NCT03614234). Two of the patients in the 2 mg/kg every four weeks extension study were treated with 1 mg/kg every two weeks.

After the approval of Elfabrio in the US and the EU, sponsorship and administration of the extension studies was transferred to Chiesi. Over time, and as Elfabrio is approved for marketing in different jurisdictions, patients switch-out of the open-label extension studies. Most of them have transferred to a commercial setting; others withdraw for other reasons. Accordingly, the 1 mg/kg every two weeks dosage extension study is now closed as most patients have transferred to commercial or expanded access programs. In addition, most of the patients that enrolled in the 2 mg/kg every four weeks dosage extension study are now being treated with Elfabrio on a commercial basis.

Pediatric FLY Study

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

Japanese RISE Study

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

Commercialization of Approved Products

Elelyso – Pfizer

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

Alfataliglicerase – Fundação Oswaldo Cruz (Fiocruz)

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

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

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

Under the Chiesi Agreements, Protalix Ltd. has received $50.0 million in upfront payments and development cost reimbursements of $45 million, and is entitled to more than $1.0 billion in potential milestone payments and tiered payments for drug product purchased

from Protalix Ltd. equal to 15% - 35% (ex-US) and 15% - 40% (US), depending on the amount of annual net sales in the applicable territories.

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

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

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

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

Product Development Pipeline

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

PEGylated Uricase (PRX-115)

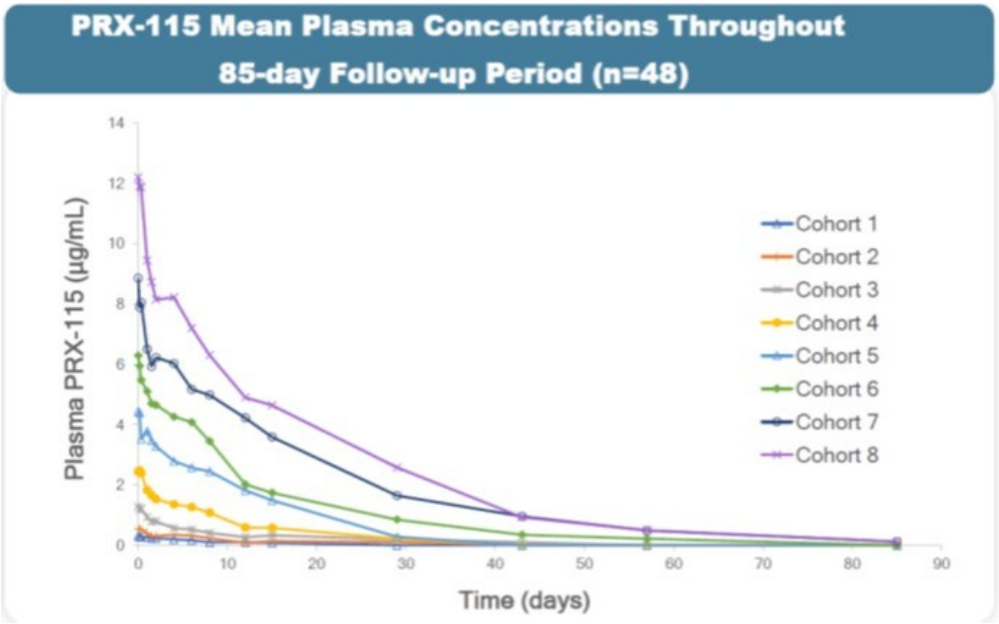
PRX-115 is our recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme under development for the potential treatment of patients with uncontrolled gout. The uricase enzyme, which does not exist naturally in humans, converts urate to allantoin, which is easily eliminated through urine.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

We have completed a phase 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 study was conducted at New Zealand Clinical Research (NZCR) under the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) and the Health and Disability Ethics Committee (HDEC) guidelines. The completed study included eight sequential dosing cohorts, each composed of eight subjects (six active and two placebo), a 3:1 ratio. Subjects in each cohort, males and females aged 18 through 65, received a single dose of PRX-115 and were analyzed for safety, pharmacokinetics (PK) and pharmacodynamics (PD) (concentrations of plasma urate) for 85 days. Overall, 64 randomized subjects were enrolled across the eight cohorts; 48 subjects were treated with PRX–115 and 16 subjects were treated with placebo.

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

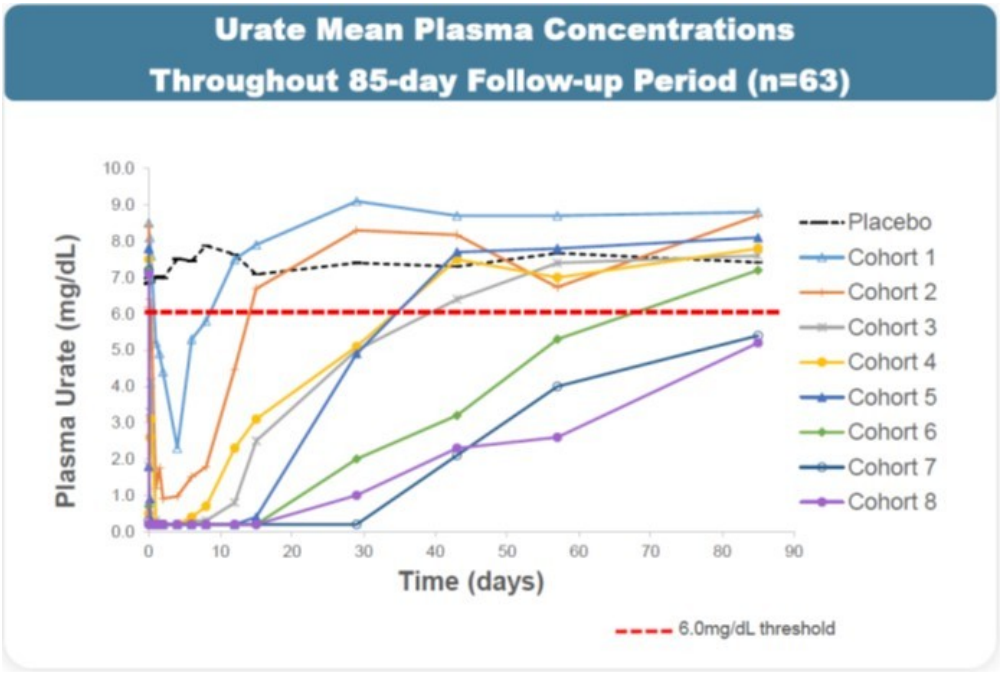
- Exposure to PRX-115 increased in a dose-dependent manner. Detectable PRX-115 levels were observed in plasma for up to 12 weeks from subjects in cohorts 6, 7, and 8. See Figure 1.

Figure 1



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

Figure 2



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

Figure 3. Overall Summary of Adverse Events*

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

*Number of subjects reporting at least one adverse event.

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

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

We have initiated preparations for a phase II clinical trial of PRX-115, and we expect to commence the study in the second half of 2025.

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

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

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

PRX-119

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

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

Intellectual Property

A key element of our overall strategy is to establish a broad portfolio of patents to protect our proprietary technology, proprietary product and product candidates and their methods of use. As of June 30, 2025, we hold a broad portfolio of 16 patent families consisting of approximately 68 patents in Europe, the United States, Israel and additional countries worldwide, as well as approximately 42 pending patent applications.

Research & Development

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

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

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

Critical Accounting Policies

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

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

Results of Operations

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

Revenues from Selling Goods

We recorded revenues from selling goods of $15.4 million during the three months ended June 30, 2025, an increase of $2.1 million, or 16%, compared to revenues of $13.3 million for the three months ended June 30, 2024. The increase resulted primarily from an increase of $8.0 million in sales to Chiesi, partially offset by a decrease of $4.7 million in sales to Fiocruz (Brazil) and of $1.2 million in sales to Pfizer.

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $0.2 million for the three months ended June 30, 2025, and June 30, 2024. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. We expect to generate minimal revenues from license and R&D services other than potential regulatory milestone payments.

Cost of Goods Sold

Cost of goods sold was $5.9 million for the three months ended June 30, 2025, a decrease of $3.6 million, or 38%, from cost of goods sold of $9.5 million for the three months ended June 30, 2024. The decrease in cost of goods sold was primarily the result of the decrease in sales to Pfizer and Fiocruz (Brazil) partially offset by the increase in sales to Chiesi.

Research and Development Expenses

For the three months ended June 30, 2025, our total research and development expenses were approximately $6.0 million comprised of approximately $3.0 million in subcontractor-related expenses, approximately $2.0 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.8 million of other expenses. For the three months ended June 30, 2024, our total research and development expenses were approximately $3.0 million comprised of approximately $1.6 million of salary and related expenses, approximately $0.5 million in subcontractor-related expenses, approximately $0.2 million of materials-related expenses and approximately $0.7 million of other expenses.

Total increase in research and developments expenses for the three months ended June 30, 2025 was $3.0 million, or 100%, compared to research and developments expenses of $3.0 million for the three months ended June 30, 2024. The increase in research and development expenses resulted primarily from preparations for the planned phase II clinical trial of PRX-115.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $2.6 million for the three months ended June 30, 2025, a decrease of $0.9 million, or 26%, compared to $3.5 million for the three months ended June 30, 2024. The decrease resulted primarily from a decrease of $0.6 million in salary and related expenses and a decrease of $0.3 million in selling expenses.

Financial Income (Expenses), Net

Financial expenses, net was $0.5 million for the three months ended June 30, 2025, compared to financial income, net of $0.2 million for the three months ended June 30, 2024. The increase in financial expenses, net resulted primarily from exchange rate costs and lower interest income on bank deposits partially offset by lower notes interest expenses due to the September 2024 repayment in full of all the outstanding principal and interest payable under the 2024 Notes.

Taxes on Income (Tax Benefit)

We recorded tax expenses of approximately $0.5 million for the three months ended June 30, 2025, compared to a tax benefit of approximately $(0.1) million for the three months ended June 30, 2024. The tax expenses or benefit resulted primarily from taxes on income mainly derived from GILTI income mainly in respect of Section 174 of the TCJA. Effective in 2022, Section 174 of the TCJA requires all U.S. companies, for tax purposes, to capitalize and subsequently amortize R&D expenses that fall within the scope of Section 174 over five years for research activities conducted in the United States and over 15 years for research activities conducted outside of the United States, rather than deducting such costs in the current year. On July 4, 2025, tax reform legislation was enacted in the United States through the passage of HR1 which includes significant corporate tax changes, including a restoration of the current deductibility for domestic research expenditures beginning in 2025, with transition options for previously capitalized amounts. We continue to evaluate the impact that the new legislation will have on the consolidated financial statements.

Six months ended June 30, 2025 compared to the six months ended June 30, 2024

Revenues from Selling Goods

We recorded revenues from selling goods of $25.4 million during the six months ended June 30, 2025, an increase of $8.4 million, or 49%, compared to revenues of $17.0 million for the six months ended June 30, 2024. The increase resulted primarily from an increase of $8.1 million in sales to Chiesi and of $4.6 million in sales to Pfizer, partially offset by a decrease of $4.3 million in sales to Fiocruz (Brazil).

Revenues from License and R&D Services

We recorded revenues from license and R&D services of $0.3 million for the six months ended June 30, 2025, an increase of $0.1 million, or 50%, compared to revenues from license and R&D services of $0.2 million for the six months ended June 30, 2024. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. We expect to generate minimal revenues from license and R&D services other than potential regulatory milestone payments.

Cost of Goods Sold

Cost of goods sold was $14.1 million for the six months ended June 30, 2025, an increase of $2.0 million, or 17%, from cost of goods sold of $12.1 million for the six months ended June 30, 2024. The increase in cost of goods sold was primarily the result of an increase in sales to Chiesi and Pfizer partially offset by a decrease in sales to Fiocruz (Brazil).

Research and Development Expenses

For the six months ended June 30, 2025, our total research and development expenses were approximately $9.5 million comprised of approximately $3.9 million of salary and related expenses, approximately $3.8 million in subcontractor-related expenses, approximately $0.4 million of materials-related expenses and approximately $1.4 million of other expenses. For the six months ended June 30, 2024, our total research and development expenses were approximately $5.8 million comprised of approximately $3.2 million of salary and related expenses, approximately $1.0 million of subcontractor-related expenses, approximately $0.3 million of materials-related expenses and approximately $1.3 million of other expenses.

Total increase in research and developments expenses for the six months ended June 30, 2025 was $3.7 million, or 64%, compared to research and developments expenses of $5.8 million for the six months ended June 30, 2024. The increase in research and development expenses resulted primarily from preparations for the planned phase II clinical trial of PRX-115.

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

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $5.2 million for the six months ended June 30, 2025, a decrease of $1.4 million, or 21%, compared to $6.6 million for the six months ended June 30, 2024. The decrease resulted primarily from a decrease of $0.9 million in salary and related expenses and a decrease of $0.5 million in selling expenses.

Financial Income (Expenses), Net

Financial expenses, net was $0.1 million for the six months ended June 30, 2025, compared to financial income, net of $0.3 million for the six months ended June 30, 2024. The decrease resulted primarily from exchange rate costs and lower interest income on bank deposits partially offset by lower notes interest expenses due to the September 2024 repayment in full of all the outstanding principal and interest payable under the 2024 Notes.

Taxes on Income (Tax Benefit)

We recorded tax expenses of approximately $0.4 million for the six months ended June 30, 2025, compared to a tax benefit of approximately $(0.2) million for the six months ended June 30, 2024. The tax expenses or benefit resulted primarily from taxes on income mainly derived from GILTI income mainly in respect of Section 174 of the TCJA. Effective in 2022, Section 174 of the TCJA requires all U.S. companies, for tax purposes, to capitalize and subsequently amortize R&D expenses that fall within the scope of Section 174 over five years for research activities conducted in the United States and over 15 years for research activities conducted outside of the United States, rather than deducting such costs in the current year. On July 4, 2025, tax reform legislation was enacted in the United States through the passage of HR1 which includes significant corporate tax changes, including a restoration of the current deductibility for domestic research expenditures beginning in 2025, with transition options for previously capitalized amounts. We continue to evaluate the impact that the new legislation will have on the consolidated financial statements.

Liquidity and Capital Resources

Our sources of liquidity include our cash balances and short-term bank deposits. At June 30, 2025, we had $33.4 million in cash and cash equivalents and short term bank deposits. In September 2024, we satisfied the outstanding principal and accrued interest under the 2024 Notes with a cash payment of approximately $21.2 million which was available primarily from the withdrawal of short term deposits. We have primarily financed our operations through sales proceeds, equity and debt financings, business collaborations, and grants funding.

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

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

Cash Flows

Net cash used in operations was $10.3 million for the six months ended June 30, 2025. The net loss for the six months ended June 30, 2025 of $3.5 million was increased by a $6.9 million increase in accounts receivable-trade and other assets, a $1.9 million decrease in accounts payable and accruals, and was offset by a $1.0 million in share-based compensation and $0.7 million in depreciation. Net cash used in investing activities for the six months ended June 30, 2025 was $0.8 million and consisted primarily of the purchase of property and equipment. Net cash provided by financing activities for the six months ended June 30, 2025 was $9.2 million and consisted of $6.8 million proceeds from issuance of Common Stock under the Sales Agreement, net and $2.4 million from the exercise of warrants and options.

Net cash provided by operations was $0.6 million for the six months ended June 30, 2024. The net loss for the six months ended June 30, 2024 of $6.8 million was increased by a $1.7 million increase in inventories, a $5.3 million increase in accounts receivable-trade and other assets and $1.0 million of financial income, net, and was offset by a $12.7 million increase in contracts liability and $2.0 million in share-based compensation. Net cash used in investing activities for the six months ended June 30, 2024 was $0.8 million and consisted primarily of the purchase of property and equipment.

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 years ended December 31, 2023 and 2024 exceeded our expenditures for the same periods.

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

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

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

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

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

Effects of Currency Fluctuations

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services and salaries expenses. We do not believe currency fluctuations have had a material effect on our results of operations during the three and six months ended June 30, 2025.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Currency Exchange Risk

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

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

	Three Months Ended June 30,		Six Months Ended June 30,		Year Ended December 31,
	2025	2024	2025	2024	2024
Average rate for period	3.581	3.725	3.597	3.694	3.700
Rate at period-end	3.372	3.759	3.372	3.759	3.647

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

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

Inherent Limitations on Effectiveness of Controls

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

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15f and 15d-15f under the Exchange Act) that occurred during the quarter ended June 30, 2025 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

We are not involved in any material legal proceedings.

Item 1A. Risk Factors

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosure

Not applicable.

Item 5. Other Information

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

Item 6. Exhibits

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File Number	Exhibit	Date	Filed or Furnished Herewith
3.1	Certificate of Incorporation of the Company	8-K	001-33357	3.1	April 1, 2016	
3.2	Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	July 1, 2016	
3.3	Second Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	October 17, 2018	
3.4	Third Amendment to Certificate of Incorporation of the Company	8-K	001-33357	3.1	December 19, 2019	
3.5	Fourth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.5	August 15, 2022	
3.6	Fifth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.6	August 7, 2023	
3.7	Second Amended and Restated Bylaws of the Company	10-Q	001-33357	3.7	May 9, 2025	
4.1†	Form of Restricted Stock Agreement/Notice	8-K	001-33357	4.1	July 18, 2012	
4.2	Description of Capital Stock	10-K	001-33357	4.7	March 14, 2024	
4.3†	Form of Stock Option Agreement (Executives)	10-Q	001-33357	4.8	August 10, 2020	
4.4	Form of Stock Option Agreement (Standard)	10-Q	001-33357	4.9	August 10, 2020	
10.1	Employment Agreement With Gilad Mamlok dated June 13, 2025	8-K	001-33357	10.1	July 21, 2025	
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X

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

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

SIGNATURES

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

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: August 14, 2025

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

Date: August 14, 2025

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: August 14, 2025

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

EXHIBIT 31.2

CERTIFICATION

I, Eyal Rubin, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2025

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

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

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

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

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

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

Date: August 14, 2025

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

EXHIBIT 32.2

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

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

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

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

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

Date: August 14, 2025

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