

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the quarterly period ended March 31, 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  
(State or other jurisdiction  
of incorporation or organization)

2 University Plaza  
Suite 100  
Hackensack, NJ  
(Address of principal executive offices)

65-0643773  
(I.R.S. Employer  
Identification No.)

07601  
(Zip Code)

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

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

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

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

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

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

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

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

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

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

On May 1, 2025, approximately 79,607,115 shares of the Registrant's common stock, \$0.001 par value, were outstanding.

**FORM 10-Q**  
**TABLE OF CONTENTS**

	<u>Page</u>
<b><u>PART I – FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements</u>	
<u>Condensed Consolidated Balance Sheets (Unaudited) – As of March 31, 2025 and December 31, 2024</u>	2
<u>Condensed Consolidated Statements of Operations (Unaudited) – For the Three Months Ended March 31, 2025 and 2024</u>	3
<u>Condensed Consolidated Statements of Changes in Stockholders’ Equity (Unaudited) – For the Three Months Ended March 31, 2025 and 2024</u>	4
<u>Condensed Consolidated Statements of Cash Flows (Unaudited) – For the Three Months Ended March 31, 2025 and 2024</u>	5
<u>Notes to Condensed Consolidated Financial Statements</u>	7
<u>Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	13
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	29
<u>Item 4. Controls and Procedures</u>	30
<b><u>PART II – OTHER INFORMATION</u></b>	
<u>Item 1. Legal Proceedings</u>	31
<u>Item 1A. Risk Factors</u>	31
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	31
<u>Item 3. Defaults Upon Senior Securities</u>	31
<u>Item 4. Mine Safety Disclosures</u>	31
<u>Item 5. Other Information</u>	31
<u>Item 6. Exhibits</u>	31
<u>Signatures</u>	33

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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)

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 19,458	\$ 19,760
Short-term bank deposits	15,285	15,070
Accounts receivable – Trade	4,675	2,909
Other assets	1,590	1,096
Inventories	19,506	21,243
Total current assets	<u>\$ 60,514</u>	<u>\$ 60,078</u>
<b>NON-CURRENT ASSETS:</b>		
Funds in respect of employee rights upon retirement	\$ 459	\$ 462
Property and equipment, net	4,725	4,591
Deferred income tax asset	2,969	2,856
Operating lease right of use assets	5,225	5,430
Total assets	<u>\$ 73,892</u>	<u>\$ 73,417</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable and accruals:		
Trade	\$ 4,121	\$ 4,533
Other	18,776	19,588
Operating lease liabilities	1,425	1,500
Total current liabilities	<u>\$ 24,322</u>	<u>\$ 25,621</u>
<b>LONG TERM LIABILITIES:</b>		
Liability for employee rights upon retirement	\$ 551	\$ 559
Operating lease liabilities	3,811	4,026
Total long term liabilities	<u>\$ 4,362</u>	<u>\$ 4,585</u>
Total liabilities	<u>\$ 28,684</u>	<u>\$ 30,206</u>
<b>COMMITMENTS</b>		
<b>STOCKHOLDERS' EQUITY</b>		
Total liabilities and stockholders' equity	<u>\$ 73,892</u>	<u>\$ 73,417</u>

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

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

	Three Months Ended	
	March 31, 2025	March 31, 2024
REVENUES FROM SELLING GOODS	\$ 9,995	\$ 3,677
REVENUES FROM LICENSE AND R&D SERVICES	118	71
TOTAL REVENUE	10,113	3,748
COST OF GOODS SOLD	(8,180)	(2,602)
RESEARCH AND DEVELOPMENT EXPENSES	(3,475)	(2,887)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(2,603)	(3,115)
OPERATING LOSS	(4,145)	(4,856)
FINANCIAL EXPENSES	(6)	(390)
FINANCIAL INCOME	419	513
FINANCIAL INCOME, NET	413	123
LOSS BEFORE TAXES ON INCOME	(3,732)	(4,733)
TAX BENEFIT	113	138
NET LOSS	\$ (3,619)	\$ (4,595)
LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	\$ (0.05)	\$ (0.06)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE (basic and diluted)	76,611,980	73,036,569

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) Number of Shares	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	Amount				
<b>Balance at January 1, 2024</b>	<u>72,952,124</u>	\$ 73	\$ 415,045	\$ (381,549)	\$ 33,569
<b>Changes during the three-month period ended March 31, 2024:</b>					
Initial adoption of ASU 2020-06			(393)	224	(169)
Share-based compensation related to stock options			500		500
Share-based compensation related to restricted stock awards	100,000	*	481		481
Net loss for the period				(4,595)	(4,595)
<b>Balance at March 31, 2024</b>	<u>73,052,124</u>	<u>\$ 73</u>	<u>\$ 415,633</u>	<u>\$ (385,920)</u>	<u>\$ 29,786</u>
<b>Balance at January 1, 2025</b>	<u>75,850,275</u>	<u>\$ 76</u>	<u>\$ 421,528</u>	<u>\$ (378,393)</u>	<u>\$ 43,211</u>
<b>Changes during the three-month period ended March 31, 2025:</b>					
Issuance of common stock under the Sales Agreement, net	1,325,179	1	2,860		2,861
Share-based compensation related to stock options			336		336
Share-based compensation related to restricted stock awards			204		204
Exercise of warrants and options	958,375	1	2,214		2,215
Net loss for the period				(3,619)	(3,619)
<b>Balance at March 31, 2025</b>	<u>78,133,829</u>	<u>\$ 78</u>	<u>\$ 427,142</u>	<u>\$ (382,012)</u>	<u>\$ 45,208</u>

\*Represents an amount equal to less than \$1.

(1) Common stock, \$0.001 par value; Authorized – as of March 31, 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)

	Three Months Ended	
	March 31, 2025	March 31, 2024
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (3,619)	\$ (4,595)
Adjustments required to reconcile net loss to net cash provided by (used in) operating activities:		
Share-based compensation	540	981
Depreciation	346	322
Financial income, net	(375)	(471)
Changes in accrued liability for employee rights upon retirement	3	8
Changes in deferred income tax asset	(113)	(138)
Gain on amounts funded in respect of employee rights upon retirement	-	(3)
Changes in operating assets and liabilities:		
Increase in contracts liability	-	11,039
Decrease (increase) in accounts receivable-trade and other assets	(2,275)	1,746
Changes in operating lease right of use assets, net	(18)	14
Decrease (increase) in inventories	1,737	(3,301)
Decrease in accounts payable and accruals	(1,284)	(1,414)
Net cash provided by (used in) operating activities	<u>\$ (5,058)</u>	<u>\$ 4,188</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	\$ (306)	\$ (598)
Amounts funded in respect of employee rights upon retirement, net	(6)	(8)
Net cash used in investing activities	<u>\$ (312)</u>	<u>\$ (606)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from issuance of common stock under the Sales Agreement, net	\$ 2,861	\$ -
Exercise of warrants and options	2,215	-
Net cash provided by financing activities	<u>\$ 5,076</u>	<u>\$ -</u>
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>	<u>\$ (8)</u>	<u>\$ (7)</u>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<u>(302)</u>	<u>3,575</u>
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	<u>19,760</u>	<u>23,634</u>
<b>BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<u><u>\$ 19,458</u></u>	<u><u>\$ 27,209</u></u>

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

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

(Continued) – 2

	Three Months Ended	
	March 31, 2025	March 31, 2024
<b>SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:</b>		
Purchase of property and equipment	\$ 427	\$ 146
Operating lease right of use assets obtained in exchange for new operating lease liabilities	\$ 33	\$ 186
<b>SUPPLEMENTARY DISCLOSURE ON CASH FLOWS</b>		
Interest paid	\$ -	\$ 766
Interest received	\$ 166	\$ 33

**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<sup>®</sup> protein expression system (“ProCellEx”). To date, the Company has successfully developed two enzyme replacement therapies (ERTs); Elfabrio<sup>®</sup> (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease and Elelyso<sup>®</sup> (taliglucerase alfa) for the treatment of adult patients with Gaucher disease. Elfabrio, which the Company referred to as PRX-102 during its development stage, has been approved for marketing in the United States, the European Union, Great Britain, Switzerland, Peru, Israel, Russia and Singapore. The Company has partnered with Chiesi Farmaceutici S.p.A. (“Chiesi”) for the development and commercialization of Elfabrio.

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

The Company is committed to leveraging its track record of success as the Company progresses with the development of treatments for rare and orphan diseases. 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.

On May 5, 2023, the European Commission (“EC”) announced that it had approved the Marketing Authorization Application (“MAA”) for Elfabrio and on May 9, 2023, the U.S. Food and Drug Administration (“FDA”) announced that it had approved the Biologics License Application (“BLA”) for Elfabrio (pegunigalsidase alfa), each for adult patients with a confirmed diagnosis of Fabry disease. Both approvals cover the 1 mg/kg every two weeks dosage.

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

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.

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.

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

Since its approval by the FDA, Eleyso has been marketed by Pfizer in accordance with the exclusive license and supply agreement entered into between Protalix Ltd. and Pfizer, which is referred to herein as the Pfizer Agreement. In October 2015, Protalix Ltd. and Pfizer entered into an amended exclusive license and supply agreement, which is referred to herein as the Amended Pfizer Agreement, pursuant to which the Company sold to Pfizer its share in the collaboration created under the Pfizer Agreement for the commercialization of Eleyso. As part of the sale, the Company agreed to transfer its rights to Eleyso 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 Eleyso, 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 March 31, 2025, shares of Common Stock for total gross proceeds of approximately \$19.7 million 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 conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel’s border with the Gaza Strip and in other areas within the State of Israel attacking a number of civilian and military targets while simultaneously launching extensive rocket attacks on the Israeli population and industrial centers. At the same time, clashes between Israel and Hezbollah in Lebanon increased. In response, Israel’s security cabinet declared war against the Hamas and a military campaign against these terrorist organizations commenced in parallel to their continued rocket and terror attacks. Moreover, the attacks by Hamas and Hezbollah, and Israel’s defensive measures, may result in a greater regional conflict. Since the outbreak of the war, other regional actors, including Iran, have taken military action against Israel. Although ceasefire negotiations are on-going 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 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 March 31, 2025, are sufficient to satisfy the Company’s capital needs for at least 12 months from the date that these financial statements are issued.

**b. Basis of presentation**

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

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

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2024, filed by the Company with the U.S. Securities and Exchange Commission (the “Commission”). 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 loss per share**

Basic and diluted loss per share (“LPS”) is computed by dividing net loss by the weighted average number of shares of Common Stock outstanding for each period. The calculation of diluted LPS does not include approximately 18,216,366 and 31,839,345 shares of Common Stock underlying outstanding options, unvested shares of restricted stock, warrants and convertible notes of the Company, as applicable, for the three months ended March 31, 2025 and March 31, 2024.

**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.

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.

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

**NOTE 2 - INVENTORIES**

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

<i>(U.S. dollars in thousands)</i>	<u>March 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
Raw materials	\$ 4,484	\$ 4,549
Work in progress	8,002	11,245
Finished goods	7,020	5,449
Total inventory	<u>\$ 19,506</u>	<u>\$ 21,243</u>

**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 sold, in the aggregate 1,325,179 shares of Common Stock under the Sales Agreement. The Company generated gross proceeds equal to approximately \$3.0 million in connection with such sales (issuance costs were \$0.1 million).
- b. 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 remain outstanding.

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

**NOTE 5 – TAX BENEFIT**

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

<i>(U.S. dollars in thousands)</i>	<b>Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Deferred taxes on income	\$ (113)	\$ (138)
Total tax benefit	\$ (113)	\$ (138)

The Company had an effective tax rate of (3)% for the three months ended March 31, 2025 and for the three months ended March 31, 2024. For the three months ended March 31, 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.

**NOTE 6 – 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:

<i>(U.S. dollars in thousands)</i>	<b>Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Revenues from customers	\$ 10,113	\$ 3,748
Less:		
Employee salaries and related expenses	5,205	5,144
Sub-contractors expense	2,689	2,155
Interest expense	6	390
Interest income	(419)	(513)
Depreciation	346	322
Other segment expenses*	6,018	983
Loss before taxes on income	(3,732)	(4,733)
Tax benefit	(113)	(138)
Segment net loss	\$ (3,619)	\$ (4,595)

\* 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:

<i>(U.S. dollars in thousands)</i>	<b>Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
<i>Gaucher disease:</i>		
Pfizer (Ireland)	\$ 6,979	\$ 1,127
Fiocruz (Brazil)	\$ 3,016	\$ 2,550
<i>Fabry disease:</i>		
Chiesi (Italy)	\$ -	\$ -
Total revenues from selling goods	\$ 9,995	\$ 3,677
Revenues from license and R&D services	\$ 118	\$ 71

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

d. Long lived assets are located in Israel.

**NOTE 7 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION**

**Balance sheets:**

<i>(U.S. dollars in thousands)</i>	<u>March 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
<b>Accounts payable and accruals – other:</b>		
Payroll and related expenses	\$ 1,346	\$ 1,343
Provision for vacation	1,878	1,811
Accrued expenses	9,349	9,568
Royalties payable	300	1,080
Income tax payable	3,476	3,476
Advances from customer	2,000	-
Payable to customer	-	2,056
Property and equipment suppliers	427	254
	<u>\$ 18,776</u>	<u>\$ 19,588</u>

**NOTE 8 – SUBSEQUENT EVENTS**

Since the end of the quarter ended March 31, 2025, the Company collected approximately \$2.8 million from sales to Pfizer and approximately \$1.9 million from sales to Fiocruz (Brazil).

Since the end of the quarter ended March 31, 2025, the Company sold, in the aggregate 1,450,036 shares of Common Stock under the Sales Agreement, generating gross proceeds equal to approximately \$4.1 million in connection with such sales.

## 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, 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<sup>®</sup> (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 U.S. Food and Drug Administration, or 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;

## [Table of Contents](#)

- 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 Inc., or Pfizer, and Chiesi Farmaceutici S.p.A., or Chiesi;
- risks related to the amount and sufficiency of our cash and cash equivalents and short-term bank deposits;
- risks relating to changes to interim, top-line or preliminary data from clinical trials that we announce or publish;
- risks relating to the compliance by Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health, or the Brazilian MoH, with its purchase obligations under our supply and technology transfer agreement, which may have a material adverse effect on us and may also result in the termination of such agreement;
- risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector;
- our dependence on performance by third-party providers of services and supplies, including without limitation, clinical trial services;
- the inherent risks and uncertainties in developing drug platforms and products of the type we are developing;
- the impact of development of competing therapies and/or technologies by other companies;
- risks related to our supply of drug products to Pfizer;
- potential product liability risks, and risks of securing adequate levels of related insurance coverage;
- the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties; and
- risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere.

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

### **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<sup>®</sup> 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<sup>®</sup> (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease and Elelyso<sup>®</sup> (taliglucerase alfa) for the treatment of adult patients 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 and Singapore. 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.

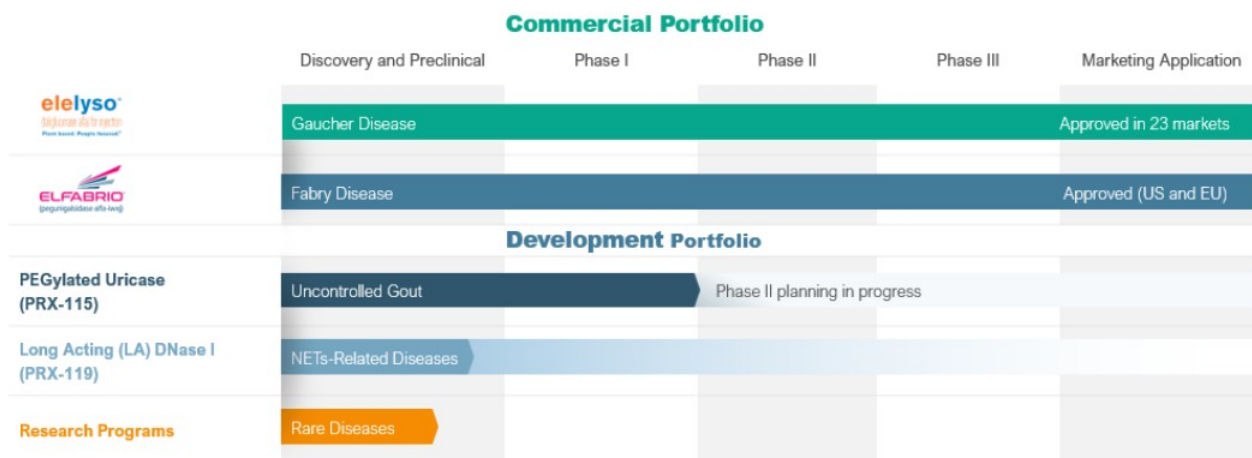
In addition, we are developing PEGylated uricase, or PRX-115, for the treatment of uncontrolled gout, Long Acting (LA) DNase I, or PRX-119, for the treatment of NETs-related diseases, and a number of other technologies and preclinical assets. We have completed a

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**

# Product Pipeline

Recombinant proteins designed to target unmet medical needs and established pharmaceutical markets



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**




**Large-Scale Plant Cell Production Advantages**

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

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**Mammalian Cell Expression**



Chinese Hamster Ovary (CHO) cell lines

- High set-up costs involving large bioreactors
- Cell cultures require a complex medium; small changes in composition may affect product characteristics
- Require highly controlled growth conditions in the bioreactor (e.g., Ph, temp and CO<sub>2</sub>)
- Susceptibility to viral contaminations

**Bacteria and Yeast Cell Expression**



Bacteria or yeast cell lines

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

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

#### **Unique Genetic Engineering Tools**

Generates improved tobacco plant cell lines expressing plant unique expression cassettes designed to produce therapeutic proteins with **optimized pharmacokinetic and pharmacodynamic profiles**

#### **Customized Chemical Modifications**

Produces complex glycosylated proteins with potentially improved biologic attributes, including **reduced immunogenicity and enhanced protein stability/activity**

#### **Intellectual Property Advantages**

Proprietary manufacturing processes and development of 2<sup>nd</sup> generation products, related to Composition of Matter protection and FTO (Freedom-to-Operate)



#### **Optimized for Complexity**

Ability to express proteins that are difficult to express in other cell-based systems

#### **Streamlined Production Process**

Simplified maintenance with **high batch-to-batch reproducibility and no risk of viral contamination**

#### **Poised for Flexible Scale-Up**

GMP-compliant infrastructure with modular capabilities allows for **rapid horizontal scale-up** to maintain production volume

### **Our Marketed Products**

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

#### ***Elelyso for the Treatment of Gaucher Disease***

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

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

The global market for Gaucher disease, that includes Sanofi's Cerezyme®, Shire's (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 -0.46% 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 and Singapore 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  $\alpha$ -galactosidase-A resulting in the progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide, or Gb<sub>3</sub>, in blood vessel walls throughout their body. The ultimate consequences of Gb<sub>3</sub> 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  $\alpha$ -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<sup>®</sup>, agalsidase alfa, Shire's Replagal<sup>®</sup> and Amicus Therapeutics' Galafold<sup>®</sup>, among others, is forecasted to be approximately \$2.3 billion in 2025 and is forecasted to grow at a CAGR of 6.6% from 2024-2030 reaching approximately \$3.1 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  $-2 \text{ mL/min/1.73 m}^2/\text{year}$  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.

## [Table of Contents](#)

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, MSSSI, 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<sup>2</sup>/year while on agalsidase alfa to -1.19 mL/min/1.73m<sup>2</sup>/year on PRX-102 in all patients. Male patients improved from -6.36 mL/min/1.73m<sup>2</sup>/year to -1.73mL/min/1.73m<sup>2</sup>/year and female patients improved from -5.03 mL/min/1.73m<sup>2</sup>/year to -0.21 mL/min/1.73m<sup>2</sup>/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<sub>3</sub> 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<sub>3</sub> 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

## [Table of Contents](#)

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<sub>3</sub> concentrations remained stable during the study with a mean change ( $\pm$ SE) of 3.01 nM (0.94) from baseline (19.36 nM  $\pm$ 3.35) to Week 52 (22.23  $\pm$ 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<sup>2</sup> (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<sup>2</sup>/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<sub>3</sub> inclusions burden and lyso-Gb<sub>3</sub> in the circulation. A high correlation was found between the two Fabry disease biomarkers, reduction of kidney Gb<sub>3</sub> inclusions and the reduction of plasma lyso-Gb<sub>3</sub> 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<sub>3</sub> 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 MSSSI, 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 MSSSI.

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 Elelyso in all markets, excluding Brazil, pursuant to the Amended Pfizer Agreement under which Pfizer retains 100% of revenue and reimburses 100% of direct costs. 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, 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.

##### *Elelyso – Fundação Oswaldo Cruz (Fiocruz)*

Elelyso, marketed as BioManguinhos alfatriglicerase 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 alfatriglicerase is the therapy of choice for newly diagnosed patients. BioManguinhos alfatriglicerase 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 alfatriglicerase. Fiocruz has not satisfied certain purchase commitments under the Brazil Agreement. Accordingly, we and Fiocruz discuss on a continuous basis, potential steps to maximize sales of BioManguinhos alfatriglicerase sales to the Brazilian MoH.

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

We have entered into two exclusive global licensing and supply agreements for PRX-102 for the treatment of Fabry disease with Chiesi; the Chiesi Ex-US Agreement and the Chiesi US Agreement, collectively, the Chiesi Agreements. Under the 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 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 its net sales, depending on the amount of annual sales, 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 its net sales under the Chiesi US Agreement to Protalix Ltd., depending on the amount of annual sales, subject to certain terms and conditions, as consideration for product supply.

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

On August 29, 2022, we entered into 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 6-month multiple dosing toxicity study in one animal species were conducted to support single- and multiple-dose studies in humans.

In March 2023, we initiated our phase I clinical trial of PRX-115 for the potential treatment of uncontrolled gout entitled “A Double-blind, Placebo-controlled, Single Ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics Properties of PRX-115 in Adult Volunteers With Elevated Uric Acid Levels” (NCT05745727), or the *FIH* study. The 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 study was initially designed to include seven 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.

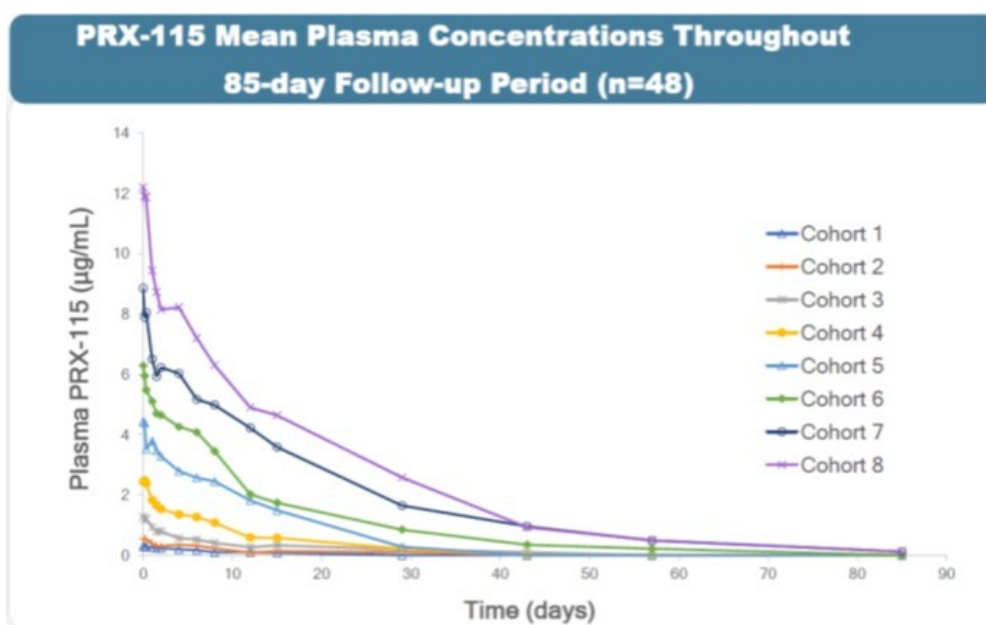
After a review of initial positive top-line results from the initial seven cohorts, and following the review and acceptance of the safety data from such seven cohorts by the safety and monitoring committee for dose escalation for the *FIH* study, we decided to expand the study by adding an eighth cohort of eight new subjects to analyze a higher dose and its potential to result in increased exposure time.

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:

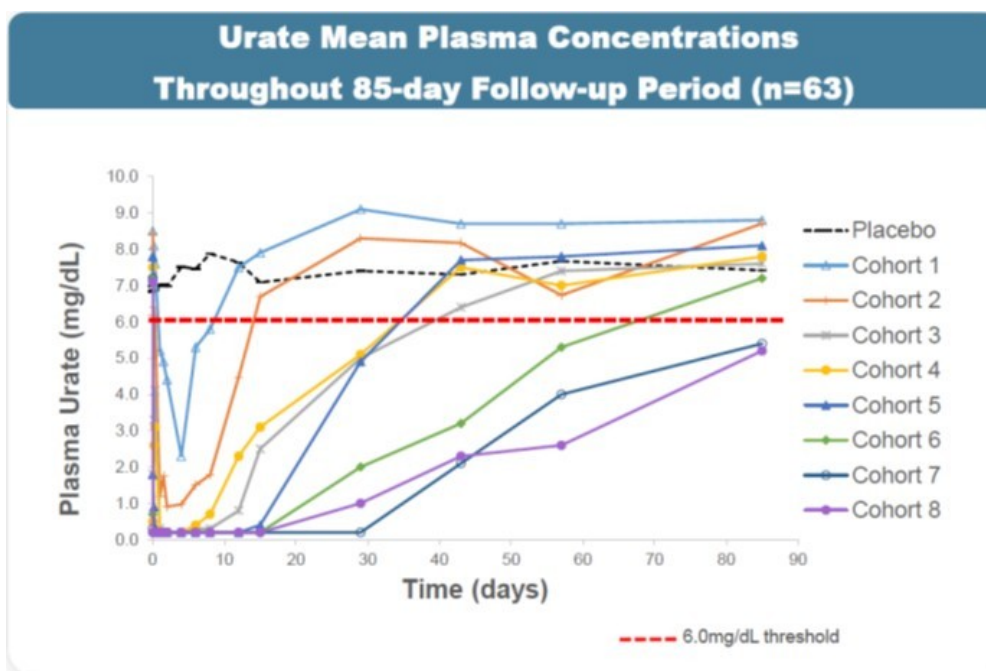
- Exposure to PRX-115 increased in a dose-dependent manner. Detectable PRX-115 levels were observed in plasma for up to 12 weeks from subjects in cohorts 6, 7, and 8. See Figure 1.

**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 cause 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<sup>®</sup> (pegloticase) for treatment of chronic gout refractory to conventional therapy (gout patients who have contraindication/failure of other lowering urate treatments) and (ii) Elitek<sup>®</sup>, 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 March 31, 2025, we hold a broad portfolio of 15 patent families consisting of approximately 67 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 March 31, 2025 compared to the three months ended March 31, 2024***

##### *Revenues from Selling Goods*

We recorded revenues from selling goods of \$10.0 million during the three months ended March 31, 2025, an increase of \$6.3 million, or 170%, compared to revenues of \$3.7 million for the three months ended March 31, 2024. The increase resulted primarily from an increase of \$5.9 million in sales to Pfizer and an increase of \$0.4 million in sales to Fiocruz (Brazil).

##### *Revenues from License and R&D Services*

We recorded revenues from license and R&D services of \$0.1 million for the three months ended March 31, 2025 and the three months ended March 31, 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 \$8.2 million for the three months ended March 31, 2025, an increase of \$5.6 million, or 215%, from cost of goods sold of \$2.6 million for the three months ended March 31, 2024. The increase in cost of goods sold was primarily the result of an increase in sales to Pfizer and Fiocruz (Brazil).

##### *Research and Development Expenses*

For the three months ended March 31, 2025, our total research and development expenses were approximately \$3.5 million comprised of approximately \$1.8 million of salary and related expenses, approximately \$0.8 million in subcontractor-related expenses, approximately \$0.2 million of materials-related expenses and approximately \$0.7 million of other expenses. For the three months ended March 31, 2024, our total research and development expenses were approximately \$2.9 million comprised of approximately \$1.5 million of salary and related expenses, approximately \$0.5 million of subcontractor-related expenses, approximately \$0.2 million of materials-related expenses and approximately \$0.7 million of other expenses.

Total increase in research and development expenses for the three months ended March 31, 2025 was \$0.6 million, or 21%, compared to the three months ended March 31, 2024. The increase in research and development expenses resulted primarily from the advance in our clinical pipeline.

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 March 31, 2025, a decrease of \$0.5 million, or 16%, compared to \$3.1 million for the three months ended March 31, 2024. The decrease resulted primarily from a decrease of \$0.4 million in salary and related expenses and a decrease of \$0.1 million in selling expenses.

### *Financial Income, Net*

Financial income, net was \$0.4 million for the three months ended March 31, 2025, compared to financial income, net of \$0.1 million for the three months ended March 31, 2024. The difference resulted primarily from lower notes interest expenses due to the September 2024 repayment in full of all the outstanding principal and interest payable under the 2024 Notes, partially offset by lower interest income on bank deposits and higher exchange rate costs.

### *Tax Benefit*

We recorded a tax benefit of approximately \$(0.1) million for the three months ended March 31, 2025 and March 31, 2024. The tax benefit resulted primarily from deferred 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.

### **Liquidity and Capital Resources**

Our sources of liquidity include our cash balances and bank deposits. At March 31, 2025, we had \$34.7 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 quarter ended March 31, 2025, we sold, in the aggregate, 1,325,179 shares of Common Stock under the Sales Agreement generating gross proceeds equal to approximately \$3.0 million. In March 2025, we amended the program to provide for the offer and sale of up to an additional \$20.0 million. In addition, during the quarter ended March 31, 2025, we issued 908,000 shares of our Common Stock in connection with the exercise of warrants issued in 2020 generating proceeds equal to approximately \$2.1 million. The warrants expired on March 11, 2025. Accordingly, no warrants remain outstanding.

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 \$5.1 million for the three months ended March 31, 2025. The net loss for the three months ended March 31, 2025 of \$3.6 million was increased by a \$1.3 million decrease in accounts payable and accruals, a \$2.3 million increase in accounts receivable-trade and other assets and \$0.4 million financial income, net and was offset by a \$0.5 million in share-based compensation, a \$1.7 million decrease in inventories and \$0.3 million in depreciation. Net cash used in investing activities for the three months ended March 31, 2025 was \$0.3 million and consisted primarily of the purchase of property and equipment. Net cash provided by financing activities for the three months ended March 31, 2025 was \$5.1 million and consisted of \$2.9 million proceeds from issuance of Common Stock under the Sales Agreement, net and \$2.2 million from the exercise of warrants and options.

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

### **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

## [Table of Contents](#)

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 period.

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. As of March 31, 2025, shares of Common Stock for total gross proceeds of approximately \$19.7 million remain available to be sold under the Sales Agreement. 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 months ended March 31, 2025.

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements as of each of March 31, 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.

## [Table of Contents](#)

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:

	<u>Three Months Ended</u>		<u>Year Ended</u>
	<u>March 31,</u>		<u>December 31,</u>
	<u>2025</u>	<u>2024</u>	<u>2024</u>
Average rate for period	3.613	3.662	3.700
Rate at period-end	3.718	3.681	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 March 31, 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 March 31, 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).

On May 8, 2025, our Board of Directors unanimously approved and adopted an amendment and restatement of our Amended and Restated Bylaws, or the Amended Bylaws, effective immediately, to (i) provide that at any meeting of stockholders called for the purpose in the manner set forth in the Amended Bylaws, any director may be removed from office, with or without cause, by a majority of the stockholders entitled to vote at an election of directors; and (ii) remove the provision that prohibits stockholders from acting by written consent.

The foregoing summary and description of the Amended Bylaws does not purport to be complete and is qualified in its entirety by reference to the full text of the Amended Bylaws, a copy of which is filed as Exhibit 3.7 to this Quarterly Report on Form 10-Q and incorporated herein by reference.

### Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed or Furnished Herewith
		Form	File Number	Exhibit	Date	
1.1	<a href="#">Letter Agreement dated March 17, 2025 to the At the Market Offering Agreement, dated February 27, 2023, between the Company and H.C. Wainwright &amp; Co., LLC</a>	8-K	001-33357	1.1	March 17, 2025	
3.1	<a href="#">Certificate of Incorporation of the Company</a>	8-K	001-33357	3.1	April 1, 2016	
3.2	<a href="#">Amendment to Certificate of Incorporation of the Company</a>	Def 14A	001-33357	Appen. A	July 1, 2016	
3.3	<a href="#">Second Amendment to Certificate of Incorporation of the Company</a>	Def 14A	001-33357	Appen. A	October 17, 2018	
3.4	<a href="#">Third Amendment to Certificate of Incorporation of the Company</a>	8-K	001-33357	3.1	December 19, 2019	
3.5	<a href="#">Fourth Amendment to Certificate of Incorporation of the Company</a>	10-Q	001-33357	3.5	August 15, 2022	
3.6	<a href="#">Fifth Amendment to Certificate of Incorporation of the Company</a>	10-Q	001-33357	3.6	August 7, 2023	

[Table of Contents](#)

3.7	<a href="#">Second Amended and Restated Bylaws of the Company</a>					X
4.1†	<a href="#">Form of Restricted Stock Agreement/Notice</a>	8-K	001-33357	4.1	July 18, 2012	
4.2	<a href="#">Description of Capital Stock</a>	10-K	001-33357	4.7	March 14, 2024	
4.3†	<a href="#">Form of Stock Option Agreement (Executives)</a>	10-Q	001-33357	4.8	August 10, 2020	
4.4	<a href="#">Form of Stock Option Agreement (Standard)</a>	10-Q	001-33357	4.9	August 10, 2020	
31.1	<a href="#">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</a>					X
31.2	<a href="#">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</a>					X
32.1	<a href="#">18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Executive Officer</a>					X
32.2	<a href="#">18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Certification of Chief Financial Officer</a>					X
101.INS	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	COVER PAGE INTERACTIVE DATA FILE (formatted as Inline XBRL and contained in Exhibit 101).					

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

**SIGNATURES**

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

PROTALIX BIOTHERAPEUTICS, INC.  
(Registrant)

Date: May 9, 2025

By: /s/ Dror Bashan

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

Date: May 9, 2025

By: /s/ Eyal Rubin

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

**SECOND AMENDED AND RESTATED  
BYLAWS  
OF  
PROTALIX BIOTHERAPEUTICS, INC.  
(Adopted May 8, 2025)**

**ARTICLE I  
OFFICES**

**Section 1.1 Registered Office.**

The registered office of the corporation in the State of Delaware shall be 1013 Centre Road, Suite 403-B, Wilmington, DE 19805, New Castle County.

**Section 1.2 Other Offices.**

The corporation shall also have and maintain an office or principal place of business at 2 Snunit Street, Science Park, P.O. Box 455, Carmiel 2161401, Israel, and may also have offices at such other places, both within and without the State of Delaware, as the Board of Directors may from time to time determine or the business of the corporation may require.

**Section 1.3 Registered Agent.**

The Board of Directors shall designate a registered agent for service of process on the corporation for the State of Delaware and for each state in which the corporation qualifies to do business.

**ARTICLE II  
STOCKHOLDERS' MEETINGS**

**Section 2.1 Place of Meetings.**

(a) Meetings of stockholders may be held at such place, either within or without this State, as may be designated by or in the manner provided in these Amended and Restated Bylaws or, if not so designated, as determined by the Board of Directors. The Board of Directors may, in its sole discretion, determine that the meeting shall not be held at any place, but may instead be held solely by means of remote communication as authorized by paragraph (b) of this **Section 2.1** **[Place of Meetings]**.

(b) If authorized by the Board of Directors in its sole discretion, and subject to such guidelines and procedures as the Board of Directors may adopt, stockholders and proxyholders not physically present at a meeting of stockholders may, by means of remote communication:

- (1) Participate in a meeting of stockholders; and
- (2) Be deemed present in person and vote at a meeting of stockholders whether such meeting is to be held at a designated place or solely by means of remote

communication, provided that (A) the corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by means of remote communication is a stockholder or proxyholder, (B) the corporation shall implement reasonable measures to provide such stockholders and proxyholders a reasonable opportunity to participate in the meeting and to vote on matters submitted to the stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings, and (C) if any stockholder or proxyholder votes or takes other action at the meeting by means of remote communication, a record of such vote or other action shall be maintained by the corporation.

For purposes of this **Section 2.1 [Place of Meetings]**, “remote communication” shall include (1) telephone or other voice communications and (2) electronic mail or other form of written or visual electronic communications satisfying the requirements of **Section 2.11(b) [Fixing Record Dates]**.

## **Section 2.2 Annual Meetings.**

The annual meetings of the stockholders of the corporation, for the purpose of election of directors and for such other business as may lawfully come before it, shall be held on such date and at such time as may be designated from time to time by the Board of Directors.

## **Section 2.3 Special Meetings.**

Special Meetings of the stockholders of the corporation, other than as required by statute, may be called at any time, for any purpose or purposes, by the Chairperson of the Board, the President or the Board of Directors, acting pursuant to a resolution adopted by majority of the whole Board of Directors.

Subject to the provisions of this **Section 2.3 [Special Meetings]**, upon written request of any stockholder or stockholders holding in the aggregate not less than 25% of all of the votes entitled to be cast on any issue proposed to be considered at the Special Meeting (“Requisite Holders”) signed, dated and delivered in person or sent by registered mail to the Chairman of the Board, President or Secretary of the corporation in a form that complies with the provisions of this **Section 2.3 [Special Meetings]** and all other applicable sections of these Amended and Restated Bylaws (a “Special Meeting Request”), the Secretary shall call a special meeting of stockholders to be held at the principal office of the corporation or at such place and at such time as the Secretary may fix, such meeting to be held not less than 30 nor more than 60 days after the receipt of such request, and if the Secretary shall neglect or refuse to call such meeting within 10 days after the receipt of such request, the stockholder making such request may do so.

The Board of Directors shall determine whether all requirements set forth in these Amended and Restated Bylaws have been satisfied and such determination shall be binding on the corporation and its stockholders. A Special Meeting Request shall only be valid if it is signed and dated by each of the stockholders that is one of the Requisite Holders and include: (i) a statement of the specific purpose(s) of the special meeting, the matter(s) proposed to be acted on at the special meeting (including the text of any resolutions proposed for consideration) and the reasons for conducting such business at the special meeting; (ii) the name and record address of

each stockholder of record signing such request, the date of each such stockholder's signature and the name and address of any beneficial owner on whose behalf such request is made; (iii) the class or series and number of shares of the corporation that are beneficially owned by each such stockholder and any such beneficial owner; (iv) any material interest of each stockholder or any such beneficial owner in any of the business proposed to be conducted at the special meeting and a description of all arrangements or understandings between any such stockholder and/or beneficial owner and any other person or persons (naming such person or persons) with respect to the business proposed to be conducted; (v) a representation that one or more of the stockholders submitting the Special Meeting Request intend to appear in person or by proxy at the special meeting to present the proposal(s) or business to be brought before the special meeting; (vi) if any stockholder submitting such request intends to solicit proxies with respect to the stockholders' proposal(s) or business to be presented at the special meeting, a representation to that effect; (vii) all information relating to each stockholder signing the Special Meeting Request that must be disclosed in solicitations for proxies for election of directors in an election contest (even if an election contest is not involved), or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"); and (viii) if the purpose of the special meeting includes the election of one or more directors, all the information such stockholder or stockholders would be required to include in a notice delivered to the corporation pursuant to **Section 2.9 [Stockholder Proposals at Annual Meetings]** and **Section 2.10 [Nominations of Persons for Election to the Board of Directors]** of these Amended and Restated Bylaws.

In addition, a Special Meeting Request shall not be valid if (i) the Special Meeting Request relates to an item of business that is not a proper subject for stockholder action under applicable law; (ii) the Special Meeting Request is received by the corporation during the period commencing 90 days prior to the first anniversary of the date of the immediately preceding annual meeting and ending on the date of the next annual meeting; (iii) an identical or similar item ("Similar Item") was presented at any meeting of stockholders held within 30 days prior to receipt by the corporation of such Special Meeting Request (and, for purposes of this clause (iii), the election of directors shall be deemed a "Similar Item" with respect to all items of business involving the election or removal of directors); (iv) a Similar Item is included in the corporation's notice as an item of business to be brought before a stockholder meeting that has been called but not yet held; or (v) such Special Meeting Request was made in a manner that involved a violation of Regulation 14A under the Exchange Act, or other applicable law.

Stockholders may revoke a Special Meeting Request by written revocation delivered to the corporation at any time prior to the special meeting; provided, however, the Board of Directors shall have the discretion to determine whether or not to proceed with the special meeting.

If none of the stockholders who submitted the Special Meeting Request for a special meeting of stockholders appears or sends a qualified representative to present the proposal(s) or business submitted by the stockholders for consideration at the special meeting, the corporation need not present such proposal(s) or business for a vote at such meeting.

## **Section 2.4 Notice of Meetings.**

(a) Except as otherwise provided by law or the corporation's Certificate of Incorporation, as amended, written notice of each meeting of stockholders, specifying the place, if any, date and hour and purpose or purposes of the meeting, and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote thereat, directed to their address as it appears upon the books of the corporation; except that where the matter to be acted on is a merger or consolidation of the corporation or a sale, lease or exchange of all or substantially all of its assets, such notice shall be given not less than 20 nor more than 60 days prior to such meeting.

(b) If at any meeting action is proposed to be taken which, if taken, would entitle stockholders fulfilling the requirements of Section 262(d) of the Delaware General Corporation Law to an appraisal of the fair value of their shares, the notice of such meeting shall contain a statement of that purpose and to that effect and shall be accompanied by a copy of that statutory section.

(c) When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such adjourned meeting, are announced at the meeting at which the adjournment is taken unless the adjournment is for more than 30 days, or unless after the adjournment a new record date is fixed for the adjourned meeting, in which event a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

(d) Notice of the time, place and purpose of any meeting of stockholders may be waived in writing, either before or after such meeting, and, to the extent permitted by law, will be waived by any stockholder by their attendance thereat, in person or by proxy. Any stockholder so waiving notice of such meeting shall be bound by the proceedings of any such meeting in all respects as if due notice thereof had been given.

(e) Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the corporation under any provision of the Delaware General Corporation Law, the corporation's Certificate of Incorporation, as amended, or these Amended and Restated Bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any such consent shall be deemed revoked if (i) the corporation is unable to deliver by electronic transmission two consecutive notices given by the corporation in accordance with such consent and (ii) such inability becomes known to the secretary or an assistant secretary of the corporation or to the transfer agent or other person responsible for the giving of notice; provided, however, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action. Notice given pursuant to this subparagraph (e) shall be deemed given: (1) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice; (2) if by electronic mail, when directed to an electronic mail address at which the

stockholder has consented to receive notice; (3) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and (4) if by any other form of electronic transmission, when directed to the stockholder. An affidavit of the Secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein. For purposes of these Amended and Restated Bylaws, "electronic transmission" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

## **Section 2.5 Quorum and Voting.**

(a) At all meetings of stockholders except where otherwise provided by law, the corporation's Certificate of Incorporation, as amended, or these Amended and Restated Bylaws, the presence, in person or by proxy duly authorized, of the holders of at least one-third (33 1/3%) of the outstanding shares of stock entitled to vote shall constitute a quorum for the transaction of business. Shares, the voting of which at said meeting have been enjoined, or which for any reason cannot be lawfully voted at such meeting, shall not be counted to determine a quorum at said meeting. In the absence of a quorum, any meeting of stockholders may be adjourned, from time to time, by vote of the holders of a majority of the shares represented thereat, but no other business shall be transacted at such meeting. At such adjourned meeting at which a quorum is present or represented, any business may be transacted which might have been transacted at the original meeting. The stockholders present at a duly called or convened meeting at which a quorum is present may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum. Abstentions and "broker non-votes" are counted as present and entitled to vote for purposes of determining a quorum. A "broker non-vote" occurs when a broker holding shares for a beneficial owner does not vote on a particular proposal because the broker does not have discretionary voting power for that particular item and has not received instructions from the beneficial owner. Abstentions and, if applicable, broker non-votes, are not counted as votes "for" or "against" any proposals.

(b) Except as otherwise provided by law, the corporation's Certificate of Incorporation, as amended, or these Amended and Restated Bylaws, action on a matter (other than the election of directors) by a voting group is approved if the votes cast within the voting group favoring the action exceed the votes cast opposing the action.

(c) Where a separate vote by a class or classes is required, at least one-third (33 1/3%) of the outstanding shares of such class or classes present in person or represented by proxy shall constitute a quorum entitled to take action with respect to that vote on that matter, and the affirmative vote of the majority of shares of such class or classes present in person or represented by proxy at the meeting shall be the act of such class.

## **Section 2.6 Voting Rights.**

(a) Except as otherwise provided by law, only persons in whose names shares entitled to vote stand on the stock records of the corporation on the record date for determining the stockholders entitled to vote at said meeting shall be entitled to vote at such meeting. Shares standing in the names of two or more persons shall be voted or represented in accordance with the determination of the majority of such persons, or, if only one of such persons is present in person or represented by proxy, such person shall have the right to vote such shares and such shares shall be deemed to be represented for the purpose of determining a quorum.

(b) Every person entitled to vote or to execute consents shall have the right to do so either in person or by an agent or agents authorized by a written proxy executed by such person or their duly authorized agent, which proxy shall be filed with the Secretary of the corporation at or before the meeting at which it is to be used. Said proxy so appointed need not be a stockholder. No proxy shall be voted on after eleven (11) months from its date unless the proxy provides for a longer period. Unless and until voted, every proxy shall be revocable at the pleasure of the person who executed it or of their legal representatives or assigns, except in those cases where an irrevocable proxy permitted by statute has been given.

(c) Without limiting the manner in which a stockholder may authorize another person or persons to act for them as proxy pursuant to subsection (b) of this section, the following shall constitute a valid means by which a stockholder may grant such authority:

(1) A stockholder may execute a writing authorizing another person or persons to act for them as proxy. Execution may be accomplished by the stockholder or their authorized officer, director, employee or agent signing such writing or causing their signature to be affixed to such writing by any reasonable means including, but not limited to, by facsimile signature.

(2) A stockholder may authorize another person or persons to act for them as proxy by transmitting or authorizing the transmission of a telephone, telegram, cablegram or other means of electronic transmission to the person who will be the holder of the proxy or to a proxy solicitation firm, proxy support service organization or like agent duly authorized by the person who will be the holder of the proxy to receive such transmission, provided that any such telephone, telegram, cablegram or other means of electronic transmission must either set forth or be submitted with information from which it can be determined that the telephone, telegram, cablegram or other electronic transmission was authorized by the stockholder. Such authorization can be established by the signature of the stockholder on the proxy, either in writing or by a signature stamp or facsimile signature, or by a number or symbol from which the identity of the stockholder can be determined, or by any other procedure deemed appropriate by the inspectors or other persons making the determination as to due authorization.

(d) Any copy, facsimile telecommunication or other reliable reproduction of the writing or transmission created pursuant to subsection (c) of this section may be substituted or used in lieu of the original writing or transmission for any and all purposes for which the original writing or transmission could be used, provided that such copy, facsimile telecommunication or other reproduction shall be a complete reproduction of the entire original writing or transmission.

## **Section 2.7 Voting Procedures and Inspectors of Elections.**

(a) The corporation shall, in advance of any meeting of stockholders, appoint one or more inspectors to act at the meeting and make a written report thereof. The corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting shall appoint one or more inspectors to act at the meeting. Each inspector, before entering upon the discharge of their duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of their ability.

(b) The inspectors shall (i) ascertain the number of shares outstanding and the voting power of each, (ii) determine the shares represented at a meeting and the validity of proxies and ballots, (iii) count all votes and ballots, (iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspectors and (v) certify their determination of the number of shares represented at the meeting and their count of all votes and ballots. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of the inspectors.

(c) The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting. No ballot, proxies or votes, nor any revocations thereof or changes thereto, shall be accepted by the inspectors after the closing of the polls unless a court of competent jurisdiction, upon application by stockholders entitled to vote at said meeting shall determine otherwise.

(d) In determining the validity and counting of proxies and ballots, the inspectors shall be limited to an examination of the proxies, any envelopes submitted with those proxies, any information provided in accordance with the Delaware General Corporation Law, ballots and the regular books and records of the corporation, except that the inspectors may consider other reliable information for the limited purpose of reconciling proxies and ballots submitted by or on behalf of banks, brokers, their nominees or similar persons which represent more votes than the holder of a proxy is authorized by the record owner to cast or more votes than the stockholder holds of record. If the inspectors consider other reliable information for the limited purpose permitted herein, the inspectors at the time they make their certification pursuant to subsection (b)(v) of this section shall specify the precise information considered by them including the person or persons from whom they obtained the information, when the information was obtained, the means by which the information was obtained and the basis for the inspectors' belief that such information is accurate and reliable.

## **Section 2.8 List of Stockholders.**

The officer who has charge of the stock ledger of the corporation shall prepare and make, or shall cause to be prepared at least 10 days before every meeting of stockholders, a complete list of the stockholders entitled to vote at said meeting showing the address of and the number of shares registered in the name of each stockholder. The corporation need not include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least 10 days prior to the meeting: (i) on a reasonably accessible electronic network, provided that the

information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours at the principal place of business of the corporation. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. If the meeting is to be held at a place other than the principal office of the corporation, the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

### **Section 2.9 Stockholder Proposals at Annual Meetings.**

(a) At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (A) specified in the corporation's notice of the annual meeting (or any supplement thereto); (B) given by or at the direction of the Board of Directors; or (C) properly brought by a stockholder of the corporation who (1) is a stockholder of record at the time of the giving of the notice required by this **Section 2.9 [Stockholder Proposals at Annual Meetings]**, on the record date for the determination of stockholders entitled to notice of the annual meeting and on the record date for the determination of stockholders entitled to vote at the annual meeting and (2) has timely complied in proper written form with the notice procedures set forth in this **Section 2.9 [Stockholder Proposals at Annual Meetings]**. In addition, for business to be properly brought before an annual meeting by a stockholder, such business must be a proper matter for stockholder action pursuant to these Amended and Restated Bylaws and applicable law. For the avoidance of doubt, clause (C) above shall be the exclusive means for a stockholder to bring business (other than business included in the corporation's proxy statement or information statement pursuant to Rule 14a-8 under the Exchange Act, or any successor thereto) before an annual meeting of stockholders.

(b) To comply with clause (C) of Section 2.9(a) above, a stockholder's notice must set forth all information required under this **Section 2.9 [Stockholder Proposals at Annual Meetings]** and must be given timely in writing to the Secretary of the corporation. To be timely, a stockholder's notice must be delivered to or mailed and received by the Secretary at the principal executive offices of the corporation not less than 45 days nor more than 75 days prior to the date on which the corporation first mailed its proxy materials or its notice of availability of proxy materials (whichever is earlier) for the previous year's annual meeting of stockholders; provided, however, that in the event that no annual meeting was held in the previous year or if the date of the annual meeting has changed by more than 30 days from the one-year anniversary of the date of the previous year's annual meeting, then, for notice by the stockholder to be timely, it must be so received by the Secretary of the corporation not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of (i) the 90th day prior to such annual meeting, or (ii) the 10th day following the day on which public announcement of the date of such annual meeting is first made. In no event will the adjournment, rescheduling, postponement or other delay of any annual meeting, or any announcement thereof, commence a new time period (or extend any time period) for the giving

of a stockholder's notice as described above. "Public announcement" means disclosure in a press release reported by a national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission (the "SEC") pursuant to Section 13, Section 14 or Section 15(d) of the Exchange Act or by such other means as is reasonably designed to inform the public or stockholders of the corporation in general of such information, including, without limitation, posting on the corporation's investor relations website.

(c) To be in proper form, a stockholder's notice to the Secretary shall set forth as to each matter the stockholder proposes to bring before the annual meeting (i) a brief description of the business desired to be brought before the annual meeting, the text of the proposed business (including the text of any resolutions proposed for consideration) and the reasons for conducting such business at the annual meeting, (ii) the name and record address of the stockholder proposing such business and any Stockholder Associated Person (as defined below), (iii) the class or series and number of shares of the corporation which are beneficially owned by the stockholder and any Stockholder Associated Person, (iv) any material interest of the stockholder or any Stockholder Associated Person in such business, (v) as to the stockholder giving the notice and any Stockholder Associated Person, whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of, or any other agreement, arrangement or understanding (including, but not limited to, any short position or any borrowing or lending of shares of stock) has been made, the effect or intent of which is to mitigate loss or increase profit to or manage the risk or benefit of stock price changes for, or to increase or decrease the voting power of, such stockholder or any such Stockholder Associated Person with respect to any share of stock of the corporation (each, a "Relevant Hedge Transaction"), (vi) as to the stockholder giving the notice and any Stockholder Associated Person, to the extent not set forth pursuant to the immediately preceding clause, (a) whether and the extent to which such stockholder or Stockholder Associated Person has direct or indirect beneficial ownership of any option, warrant, convertible security, stock appreciation right, or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class or series of shares of the corporation, whether or not such instrument or right shall be subject to settlement in the underlying class or series of capital stock of the corporation or otherwise, or any other direct or indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of the corporation (a "Derivative Instrument"), (b) any rights to dividends on the shares of the corporation owned beneficially by such stockholder that are separated or separable from the underlying shares of the corporation, (c) any proportionate interest in shares of the corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder is a general partner or, directly or indirectly, beneficially owns an interest in a general partner and (d) any performance-related fees (other than an asset-based fee) that such stockholder is entitled to based on any increase or decrease in the value of shares of the corporation or Derivative Instruments, if any, as of the date of such notice, including without limitation any such interests held by members of such stockholder's immediate family sharing the same household (which information shall be supplemented by such stockholder and beneficial owner, if any, not later than 10 days after the record date for the meeting to disclose such ownership as of the record date), and (vii) a statement whether either such stockholder or any Stockholder Associated Person will deliver a proxy statement and form of proxy to holders of at least the percentage of the corporation's voting shares required under applicable law to carry the proposal (such information provided and statements made as required by clauses (i) through (vii)), a "Business

Solicitation Statement”). In addition, to be in proper written form, a stockholder’s notice to the Secretary must be supplemented not later than 10 days following the record date for the determination of stockholders entitled to notice of the meeting to disclose the information contained in clauses (iii), (v) and (vi) above as of such record date.

For purposes of this **Section 2.9 [Stockholder Proposals at Annual Meetings]** and **Section 2.10 [Nominations of Persons for Election to the Board of Directors]**, “Stockholder Associated Person” of any stockholder shall mean (i) any person controlling or controlled by, directly or indirectly, or acting in concert with, such stockholder, (ii) any beneficial owner of shares of stock of the corporation owned of record or beneficially by such stockholder and (iii) any person controlling, controlled by or under common control with such Stockholder Associated Person.

(d) Notwithstanding anything in these Amended and Restated Bylaws to the contrary, no business shall be conducted at the annual meeting except in accordance with the procedures set forth in **Section 2.1 [Place of Meetings]** and this **Section 2.9 [Stockholder Proposals at Annual Meetings]**; provided, however, that nothing in this **Section 2.9 [Stockholder Proposals at Annual Meetings]** shall be deemed to preclude discussion by any stockholder of any business properly brought before the annual meeting in accordance with said procedure. In addition, business proposed to be brought by a stockholder may not be brought before the annual meeting if such stockholder or a Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Business Solicitation Statement applicable to such business or if the Business Solicitation Statement applicable to such business contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The Chairperson of an annual meeting shall, if the facts warrant, determine and declare to the meeting that business was not properly brought before the meeting in accordance with the provisions of **Section 2.1 [Place of Meetings]** and this **Section 2.9 [Stockholder Proposals at Annual Meetings]**, and if the Chairperson should so determine they shall so declare to the meeting, and any such business not properly brought before the meeting shall not be transacted.

Nothing in this **Section 2.9 [Stockholder Proposals at Annual Meetings]** shall affect the right of a stockholder to request inclusion of a proposal in the corporation’s proxy statement or information statement to the extent that such right is provided by an applicable rule of the SEC. Nothing in this **Section 2.9 [Stockholder Proposals at Annual Meetings]** and **Section 2.10 [Nominations of Persons for Election to the Board of Directors]** shall be deemed to affect any right of the corporation to omit a proposal from the corporation’s proxy statement pursuant to Rule 14a-8 (or any successor provision) under the Exchange Act.

#### **Section 2.10 Nominations of Persons for Election to the Board of Directors.**

(a) In addition to any other applicable requirements, only persons who are nominated in accordance with the following procedures shall be eligible for election or re-election as directors at an annual meeting of stockholders. Nominations of persons for election to the Board of Directors of the corporation may be made at a meeting of stockholders only (A) by or at the direction of the Board of Directors, (B) by any nominating committee or person appointed by the Board of Directors or (C) by any stockholder of the corporation entitled to vote for the election

of directors at the meeting who complies with the notice procedures set forth in this **Section 2.10 [Nominations of Persons for Election to the Board of Directors]**.

(b) To comply with clause (C) of Section 2.10(a) above, such nominations to be made by a stockholder shall be made pursuant to timely notice in writing to the Secretary of the corporation, which shall be the exclusive means for a stockholder to make nominations whether or not the stockholder is seeking to have a proposal included in the corporation's proxy statement or information statement under an applicable rule of the SEC, including, but not limited to, Regulation 14A or Regulation 14C under the Exchange Act. To be timely, a stockholder's notice must be delivered to or mailed and received at the principal executive offices of the corporation, not less than 45 days nor more than 75 days prior to the date on which the corporation first mailed its proxy materials (or, in the absence of proxy materials, its notice of the meeting) for the previous year's annual meeting of stockholders (or the date on which the corporation mails such materials for the current year if during the prior year the corporation did not hold an annual meeting or if the date of the annual meeting was changed more than 30 days from the prior year).

(c) To be in proper written form, such stockholder's notice shall set forth:

(1) as to each person whom the stockholder proposes to nominate for election or re-election as a director (a "nominee"), (i) the name, age, business address and residence address of the nominee, (ii) the principal occupation or employment of the nominee, (iii) the class or series and number of shares of the corporation which are beneficially owned by the nominee and any derivative positions held or beneficially held by the nominee, (iv) whether and the extent to which any hedging or other transaction or series of transactions has been entered into by or on behalf of the nominee with respect to any securities of the corporation, and a description of any other agreement, arrangement or understanding (including any short position or any borrowing or lending of shares), the effect or intent of which is to mitigate loss to, or to manage the risk or benefit of share price changes for, or to increase or decrease the voting power of the nominee, (v) a description of all arrangements or understandings between or among the stockholder, any nominee or any other person or persons (naming such person or persons) pursuant to which the nominations are to be made by the stockholder, including a description of any compensatory, payment or other financial agreement, arrangement or understanding involving the nominee and of any compensation or other payment received by or on behalf of the nominee, in each case in connection with candidacy or service as a director of the corporation (a "Third-Party Compensation Arrangement"), (vi) a written statement executed by the nominee consenting to (A) being named as a nominee of such stockholder, (B) serving as a director of the corporation if elected and (C) being named in the corporation's form of proxy pursuant to Rule 14a-19 under the Exchange Act ("Rule 14a-19"), and (G) any other information relating to the nominee that would be required to be disclosed about such nominee if proxies were being solicited for the election of the nominee as a director, or that is otherwise required, in each case pursuant to Section 14 of the Exchange Act;

(2) as to the stockholder giving the notice, (i) the information required to be provided pursuant to clauses (ii) through (vi) of Section 2.9(c) above, and the supplement referenced in the last sentence of Section 2.9(c) above (except that the references to "business" in such clauses shall instead refer to nominations of directors for purposes of this paragraph), and (ii) a representation and undertaking as to whether such stockholder or Stockholder Associated

Person or others acting in concert with them intends, or is part of a group that intends, to (A) deliver a proxy statement or form of proxy to or otherwise solicit proxies from holders of at least the percentage of the voting power of the corporation's then outstanding stock required to elect such nominee(s) (which representation and undertaking must include a statement as to whether such stockholder or any Stockholder Associated Person intends to solicit the requisite percentage of the voting power of the corporation's stock under Rule 14a-19), or (B) otherwise solicit proxies from stockholders in support of such nomination (such information provided and statements made as required by Section 2.10(c)(1) and this Section 2.10(c)(2), a "Nominee Solicitation Statement").

(d) At the request of the Board of Directors, any person nominated by a stockholder for election as a director must furnish to the Secretary of the corporation (i) that information required to be set forth in the stockholder's notice of nomination of such person as a director as of a date subsequent to the date on which the notice of such person's nomination was given, (ii) a signed and completed written questionnaire (in the form provided by the Secretary at the written request of the nominating stockholder, which form will be provided by the Secretary within 10 days of receiving such request) containing information regarding such nominee's background and qualifications and such other information as may reasonably be required by the corporation to determine the eligibility of such proposed nominee to serve as an independent director of the corporation or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such nominee, (3) a written representation and undertaking that, unless previously disclosed to the corporation, such nominee is not, and will not become, a party to any Third-Party Compensation Arrangement, and (4) a written representation and undertaking that, if elected as a director, such nominee would be in compliance, and will continue to comply, with the corporation's corporate governance guidelines as disclosed on the corporation's website, as amended from time to time; in the absence of the furnishing of such information if requested, such stockholder's nomination shall not be considered in proper form and shall be ineligible for consideration at the annual meeting pursuant to this **Section 2.10 [Nominations of Persons for Election to the Board of Directors]**.

(e) No person shall be eligible for election as a director of the corporation unless nominated in accordance with the procedures set forth herein.

(f) These provisions shall not apply to nomination of any persons entitled to be separately elected by holders of preferred stock. In addition, a nominee shall not be eligible for election or re-election if a stockholder or Stockholder Associated Person, as applicable, takes action contrary to the representations made in the Nominee Solicitation Statement applicable to such nominee or in any other notice to the corporation or if the Nominee Solicitation Statement applicable to such nominee or any other relevant notice contains an untrue statement of a material fact or omits to state a material fact necessary to make the statements therein not misleading. The Chairperson of the meeting shall, if the facts warrant, determine and declare to the meeting that a nomination was not made in accordance with the foregoing procedure, and if they should so determine, they shall so declare to the meeting and the defective nomination shall be disregarded.

(g) No later than five business days prior to the annual meeting or any adjournment, rescheduling, postponement or other delay thereof, a stockholder nominating individuals for

election as a director will provide the corporation with reasonable evidence that such stockholder has met the requirements of Rule 14a-19. The failure to timely provide such update, supplement, evidence or additional information shall result in the nomination no longer being eligible for consideration at the annual meeting. If the stockholder fails to comply with the requirements of Rule 14a-19 (including because the stockholder fails to provide the corporation with all information or notices required by Rule 14a-19), then the Chairperson of the meeting may determine that the director nominees proposed by such stockholder shall be ineligible for election at the annual meeting and any votes or proxies in respect of such nomination shall be disregarded, notwithstanding that such proxies may have been received by the corporation and counted for the purposes of determining quorum.

#### **Section 2.11 Fixing Record Dates.**

(a) In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall not be more than 60 nor less than 10 days before the date of such meeting. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day preceding the day on which notice is given, or, if notice is waived, at the close of business on the day preceding the date on which the meeting is held. A determination of stockholders of record entitled notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting, subject to the Act.

(b) In order that the corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of stock, or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than 60 days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

### **ARTICLE III DIRECTORS**

#### **Section 3.1 Number and Term of Office.**

The number of directors which shall constitute the whole of the Board of Directors shall be fixed from time to time by resolution of the Board of Directors. With the exception of the first Board of Directors, which was elected by the incorporators, and except as provided in Section 3.3 of this **Article III [DIRECTORS]**, the directors shall be elected by a plurality vote of the shares represented in person or by proxy at the stockholders annual meeting in each year and entitled to vote on the election of directors. Elected directors shall hold office until the next annual meeting and until their successors shall be duly elected and qualified. Directors need not

be stockholders. If, for any cause, the Board of Directors shall not have been elected at an annual meeting, they may be elected as soon thereafter as convenient at a special meeting of the stockholders called for that purpose in the manner provided in these Amended and Restated Bylaws.

### **Section 3.2 Powers.**

The powers of the corporation shall be exercised, its business conducted and its property controlled by or under the direction of the Board of Directors.

### **Section 3.3 Vacancies.**

Vacancies and newly created directorships resulting from any increase in the authorized number of directors may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and each director so elected shall hold office for the unexpired portion of the term of the director whose place shall be vacant and until a successor shall have been duly elected and qualified. A vacancy in the Board of Directors shall be deemed to exist under this section in the case of the death, removal or resignation of any director, or if the stockholders fail at any meeting of stockholders at which directors are to be elected (including any meeting referred to in **Section 3.4 [Resignations and Removals]** below) to elect the number of directors then constituting the whole Board of Directors.

### **Section 3.4 Resignations and Removals.**

(a) Any director may resign at any time by delivering their resignation to the Board of Directors, the Chairperson of the Board, or the Secretary in writing or by electronic transmission, such resignation to specify whether it will be effective at a particular time, upon receipt or at the pleasure of the Board of Directors. If no such specification is made it shall be deemed effective at the pleasure of the Board of Directors. When one or more directors shall resign from the Board of Directors effective at a future date, a majority of the directors then in office, including those who have so resigned (prior to the resignation being in effect), shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office for the unexpired portion of the term of the director whose place shall be vacated and until a successor shall have been duly elected and qualified.

(b) At any meeting of stockholders called for the purpose in the manner hereinabove provided, any director may be removed from office, with or without cause, by a majority of the stockholders entitled to vote at an election of directors, and a new director may be elected by of the stockholders in the manner provided by these Amended and Restated Bylaws.

### **Section 3.5 Meetings.**

(a) The annual meeting of the Board of Directors shall be held immediately after the annual stockholders' meeting and at the place where such meeting is held or at the place announced by the Chairperson at such meeting. No notice of an annual meeting of the Board of Directors shall be necessary, and such meeting shall be held for the purpose of electing officers and transacting such other business as may lawfully come before it.

(b) Except as hereinafter otherwise provided, regular meetings of the Board of Directors shall be held in the principal office of the corporation. Regular meetings of the Board of Directors may also be held at any place, within or without the United States, as determined by the Chairperson of the Board or by the written consent of all directors.

(c) Special meetings of the Board of Directors may be held at any time and place within or without the State of Delaware whenever called by the Chairperson of the Board or, if there is no Chairperson of the Board, by the Chief Executive Officer, or by any of the directors.

(d) Written notice of the time and place of all regular and special meetings of the Board of Directors shall be delivered personally to each director or sent by telegram or facsimile transmission or other form of electronic transmission at least 48 hours before the start of the meeting, or sent by first class mail at least 120 hours before the start of the meeting. Notice of any meeting may be waived in writing at any time before or after the meeting and will be waived by any director by attendance thereat.

### **Section 3.6 Quorum and Voting.**

(a) A quorum of the Board of Directors shall consist of a majority of the exact number of directors fixed from time to time in accordance with Section 3.1 of **Article III [DIRECTORS]** of these Amended and Restated Bylaws, but not less than one; provided, however, at any meeting whether a quorum be present or otherwise, a majority of the directors present may adjourn from time to time until the time fixed for the next regular meeting of the Board of Directors, without notice other than by announcement at the meeting.

(b) At each meeting of the Board of Directors at which a quorum is present, all questions and business shall be determined by a vote of a majority of the directors present, unless a different vote be required by law, the corporation's Certificate of Incorporation, as amended, or these Amended and Restated Bylaws.

(c) Any member of the Board of Directors, or of any committee thereof, may participate in a meeting by means of conference telephone or other communication equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting by such means shall constitute presence in person at such meeting.

(d) The transactions of any meeting of the Board of Directors, or any committee thereof, however called or noticed, or wherever held, shall be as valid as though had at a meeting duly held after regular call and notice if a quorum be present and if, either before or after the meeting, each of the directors not present shall sign a written waiver of notice, or a consent to holding such meeting, or an approval of the minutes thereof. All such waivers, consents or approvals shall be filed with the corporate records or made a part of the minutes of the meeting.

### **Section 3.7 Action Without Meeting.**

Unless otherwise restricted by the corporation's Certificate of Incorporation, as amended, or these Amended and Restated Bylaws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting,

if all members of the Board of Directors or of such committee, as the case may be, consent thereto in writing or by electronic transmission, and such writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

### **Section 3.8 Fees and Compensation.**

Directors and members of committees may receive such compensation, if any, for their services, and such reimbursement for expenses, as may be fixed or determined by resolution of the Board of Directors.

### **Section 3.9 Committees.**

(a) **Other Committees:** The Board of Directors may, from time to time, appoint such committees as may be permitted by law. Such other committees appointed by the Board of Directors shall have such powers and perform such duties as may be prescribed by the resolution or resolutions creating such committee.

(b) **Term:** The terms of members of all committees of the Board of Directors shall expire on the date of the next annual meeting of the Board of Directors following their appointment; provided, that they shall continue in office until their successors are appointed. The Board of Directors, subject to the provisions of subsection (a) of this **Section 3.9 [Committees]**, may at any time increase or decrease the number of members of a committee or terminate the existence of a committee; provided, that no committee shall consist of less than two members. The membership of a committee member shall terminate on the date of their death or voluntary resignation, but the Board of Directors may at any time for any reason remove any individual committee member and the Board of Directors may fill any committee vacancy created by death, resignation, removal or increase in the number of members of the committee. The Board of Directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee.

(c) **Meetings:** Unless the Board of Directors shall otherwise provide, regular meetings of the committees appointed pursuant to this **Section 3.9 [Committees]** shall be held at such times and places as are determined by the Board of Directors, or by any such committee, and when notice thereof has been given to each member of such committee, no further notice of such regular meetings need be given thereafter; special meetings of any such committee may be held at the principal office of the corporation required to be maintained pursuant to Section 1.2 of **Article I [OFFICES]** hereof; or at any place which has been designated from time to time by resolution of such committee or by written consent of all members thereof, and may be called by any director who is a member of such committee upon written notice to the members of such committee of the time and place of such special meeting given in the manner provided for the giving of written notice to members of the Board of Directors of the time and place of special meetings of the Board of Directors. Notice of any special meeting of any committee may be waived in writing at any time after the meeting and will be waived by any director by attendance thereat. A majority of the authorized number of members of any such committee shall constitute

a quorum for the transaction of business, and the act of a majority of those present at any meeting at which a quorum is present shall be the act of such committee.

## **ARTICLE IV OFFICERS**

### **Section 4.1 Officers Designated.**

The officers of the corporation shall be a President, a Secretary and a Treasurer. The Board of Directors may also appoint a Chairperson of the Board, a chief executive officer, chief financial officer, one or more Vice-Presidents, assistant secretaries, assistant treasurers, and such other officers and agents with such powers and duties as the Board of Directors or the President shall deem appropriate or necessary. The order of the seniority of the Vice- Presidents shall be in the order of their nomination unless otherwise determined by the Board of Directors. The Board of Directors may assign such additional titles to one or more of the officers as they shall deem appropriate. Any one person may hold any number of offices of the corporation at any one time unless specifically prohibited therefrom by law. The salaries and other compensation of the officers of the corporation shall be fixed by or in the manner designated by the Board of Directors, or a committee thereof.

### **Section 4.2 Tenure and Duties of Officers.**

(a) **General:** All officers shall hold office at the pleasure of the Board of Directors and until their successors shall have been duly elected and qualified, unless sooner removed. Any officer may be removed at any time by the Board of Directors. If the office of any officer becomes vacant for any reason, the vacancy may be filled by the Board of Directors. Nothing in these Amended and Restated Bylaws shall be construed as creating any kind of contractual right to employment with the corporation.

(b) **Duties of the Chairperson of the Board of Directors:** The Chairperson of the Board of Directors (if there be such an officer appointed) when present shall preside at all meetings of the stockholders and the Board of Directors. The Chairperson of the Board of Directors shall perform such other duties and have such other powers as the Board of Directors shall designate from time to time.

(c) **Duties of President:** The President shall be the chief executive officer of the corporation and, in the absence of the Chairperson of the Board, and shall preside at all meetings of the stockholders and at all meetings of the Board of Directors, unless the Chairperson of the Board of Directors has been appointed and is present. The President shall perform such other duties and have such other powers as the Board of Directors shall designate from time to time.

(d) **Duties of Vice-Presidents:** The Vice-Presidents, in the order of their seniority, may assume and perform the duties of the President in the absence or disability of the President or whenever the office of the President is vacant. The Vice-President shall perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

(e) **Duties of Secretary:** The Secretary shall attend all meetings of the stockholders and, if invited, of the Board of Directors and each committee thereof, and shall record all acts and proceedings thereof in the minute book of the corporation, which may be maintained in either paper or electronic form. The Secretary shall give notice, in conformity with these Amended and Restated Bylaws, of all meetings of the stockholders and of all meetings of the Board of Directors and any Committee thereof requiring notice. The Secretary shall perform such other duties and have such other powers as the Board of Directors shall designate from time to time. The President may direct any assistant secretary to assume and perform the duties of the Secretary in the absence or disability of the Secretary, and each assistant secretary shall perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

(f) **Duties of Treasurer:** The Treasurer shall keep or cause to be kept the books of account of the corporation in a thorough and proper manner, and shall render statements of the financial affairs of the corporation in such form and as often as required by the Board of Directors or the President. The Treasurer, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the corporation. The Treasurer shall perform all other duties commonly incident to their office and shall perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time. The President may direct any assistant treasurer to assume and perform the duties of the Treasurer in the absence or disability of the Treasurer, and each assistant treasurer shall perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

**ARTICLE V**  
**EXECUTION OF CORPORATE INSTRUMENTS, AND**  
**VOTING OF SECURITIES OWNED BY THE CORPORATION**

**Section 5.1 Execution of Corporate Instruments.**

(a) The Board of Directors may in its discretion determine the method and designate the signatory officer or officers, or other person or persons, to execute any corporate instrument or document, or to sign the corporate name without limitation, except where otherwise provided by law, and such execution or signature shall be binding upon the corporation.

(b) Unless otherwise specifically determined by the Board of Directors or otherwise required by law, formal contracts of the corporation, promissory notes, deeds of trust, mortgages and other evidences of indebtedness of the corporation, and other corporate instruments or documents requiring the corporate seal, and certificates of shares of stock owned by the corporation, shall be executed, signed or endorsed by the Chairperson of the Board (if there be such an officer appointed) or by the President; such documents may also be executed by any Vice-President and by the Secretary or Treasurer or any assistant secretary or assistant treasurer. All other instruments and documents requiring the corporate signature but not requiring the corporate seal may be executed as aforesaid or in such other manner as may be directed by the Board of Directors.

(c) All checks and drafts drawn on banks or other depositories on funds to the credit of the corporation or in special accounts of the corporation shall be signed by such person or persons as the Board of Directors shall authorize so to do.

(d) Execution of any corporate instrument may be effected in such form, either manual, facsimile or electronic signature, as may be authorized by the Board of Directors.

#### **Section 5.2 Voting of Securities Owned by Corporation.**

All stock and other securities of other corporations owned or held by the corporation for itself or for other parties in any capacity shall be voted, and all proxies with respect thereto shall be executed, by the person authorized so to do by resolution of the Board of Directors or, in the absence of such authorization, by the Chairperson of the Board (if there be such an officer appointed), or by the President, or by any Vice-President.

### **ARTICLE VI SHARES OF STOCK**

#### **Section 6.1 Form and Execution of Certificates.**

Shares of stock of the corporation shall be represented by certificates, or shall be uncertificated shares that may be evidenced by a book-entry system maintained by the registrar of such stock, or a combination of both. To the extent that shares are represented by certificates, such certificates shall be in a form approved by the Board of Directors. Each certificate shall be signed in the name of the corporation by (A) the Chairperson or Vice Chairperson of the Board or the President or a Vice President and (B) the Secretary or an Assistant Secretary or the Treasurer or an Assistant Treasurer, and sealed with the seal of the corporation (which seal may be a facsimile, engraved or printed); provided, however, that where any such certificate is countersigned by a transfer agent other than the corporation or one of its employees, or is registered by a registrar other than the corporation or one of its employees, the signature of the officers of the corporation upon such certificates may be facsimiles, engraved or printed. In case any officer who shall have signed or whose facsimile signature has been placed upon such certificates shall have ceased to be such officer before such certificates shall be issued, they may nevertheless be issued by the corporation with the same effect as if such officer were still in office at the date of their issue.

#### **Section 6.2 Lost Certificates.**

The Board of Directors may direct a new certificate or certificates (or uncertificated shares in lieu of a new certificate) to be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost or destroyed. When authorizing such issue of a new certificate or certificates (or uncertificated shares in lieu of a new certificate), the Board of Directors may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost or destroyed certificate or certificates, or their legal representative, to indemnify the corporation in such manner as it shall require and/or to give the corporation a surety bond in such form and amount as it may direct as indemnity against any claim that may be

made against the corporation with respect to the certificate alleged to have been lost or destroyed.

### **Section 6.3 Transfers.**

Subject to any restrictions on transfer and unless otherwise provided by the Board of Directors, shares of stock may be transferred only on the books of the corporation by the surrender to the corporation or its transfer agent of shares in certificated form, properly endorsed or accompanied by a written assignment or power of attorney properly executed, with transfer stamps (if necessary) affixed, or upon proper instructions from the holder of uncertificated shares, in each case with such proof of the authenticity of signature as the corporation or its transfer agent may reasonably require. Except as otherwise provided by applicable law, the corporation shall be entitled to recognize the exclusive right of a person in whose name any share or shares stand on the record of stockholders as the owner of such share or shares for all purposes, including, without limitation, the rights to receive dividends or other distributions and to vote as such owner, and the corporation may hold any such stockholder of record liable for calls and assessments and the corporation shall not be bound to recognize any equitable or legal claim to or interest in any such share or shares on the part of any other person whether or not it shall have express or other notice thereof. Whenever any transfers of shares shall be made for collateral security and not absolutely, and both the transferor and transferee request the corporation to do so, such fact shall be stated in the entry of the transfer.

### **Section 6.4 Registered Stockholders.**

The corporation shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of the State of Delaware.

## **ARTICLE VII OTHER SECURITIES OF THE CORPORATION**

All bonds, debentures and other corporate securities of the corporation, other than stock certificates, may be signed by the Chairperson of the Board (if there be such an officer appointed), or the President or any Vice-President or such other person as may be authorized by the Board of Directors and the corporate seal impressed thereon or a facsimile of such seal imprinted thereon and attested by the signature of the Secretary or an assistant secretary, or the Treasurer or an assistant treasurer; provided, however, that where any such bond, debenture or other corporate security shall be authenticated by the manual signature of a trustee under an indenture pursuant to which such bond, debenture or other corporate security shall be issued, the signature of the persons signing and attesting the corporate seal on such bond, debenture or other corporate security may be the imprinted facsimile of the signatures of such persons. Interest coupons appertaining to any such bond, debenture or other corporate security, authenticated by a trustee as aforesaid, shall be signed by the Treasurer or an assistant treasurer of the corporation, or such other person as may be authorized by the Board of Directors, or bear imprinted thereon the facsimile signature of such person. In case any officer who shall have signed or attested any

bond, debenture or other corporate security, or whose facsimile signature shall appear thereon has ceased to be an officer of the corporation before the bond, debenture or other corporate security so signed or attested shall have been delivered, such bond, debenture or other corporate security nevertheless may be adopted by the corporation and issued and delivered as though the person who signed the same or whose facsimile signature shall have been used thereon had not ceased to be such officer of the corporation.

## **ARTICLE VIII INDEMNIFICATION OF OFFICERS, DIRECTORS, EMPLOYEES AND AGENTS**

### **Section 8.1 Right to Indemnification.**

Each person who was or is a party or is threatened to be made a party to or is involved (as a party, witness, or otherwise), in any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative (hereinafter a "Proceeding"), by reason of the fact that they, or a person of whom they are the legal representative, is or was a director, officer, employee, or agent of the corporation or is or was serving at the request of the corporation as a director, officer, employee, or agent of another corporation or of a partnership, joint venture, trust, or other enterprise, including service with respect to employee benefit plans, whether the basis of the Proceeding is alleged action in an official capacity as a director, officer, employee, or agent or in any other capacity while serving as a director, officer, employee, or agent (hereafter an "Agent"), shall be indemnified and held harmless by the corporation to the fullest extent authorized by the Delaware General Corporation Law, as the same exists or may hereafter be amended or interpreted (but, in the case of any such amendment or interpretation, only to the extent that such amendment or interpretation permits the corporation to provide broader indemnification rights than were permitted prior thereto) against all expenses, liability, and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties, and amounts paid or to be paid in settlement, and any interest, assessments, or other charges imposed thereon, and any federal, state, local, or foreign taxes imposed on any Agent as a result of the actual or deemed receipt of any payments under this Article) reasonably incurred or suffered by such person in connection with investigating, defending, being a witness in, or participating in (including on appeal), or preparing for any of the foregoing in, any Proceeding (hereinafter "Expenses"); provided, however, that except as to actions to enforce indemnification rights pursuant to Section 8.3 of this Article, the corporation shall indemnify any Agent seeking indemnification in connection with a Proceeding (or part thereof) initiated by such person only if the Proceeding (or part thereof) was authorized by the Board of Directors of the corporation. The right to indemnification conferred in this Article shall be a contract right.

### **Section 8.2 Authority to Advance Expenses.**

Expenses incurred by an officer or director (acting in their capacity as such) in defending a Proceeding shall be paid by the corporation in advance of the final disposition of such Proceeding; provided, however, that if required by the Delaware General Corporation Law, such Expenses shall be advanced only upon delivery to the corporation of an undertaking by or on behalf of such director or officer to repay such amount if it shall ultimately be determined that they are not entitled to be indemnified by the corporation as authorized in this Article or otherwise. Expenses incurred by other Agents of the corporation (or by the directors or officers

not acting in their capacity as such, including service with respect to employee benefit plans) may be advanced upon such terms and conditions as the Board of Directors deems appropriate. Any obligation to reimburse the corporation for Expense advances shall be unsecured and no interest shall be charged thereon.

**Section 8.3 Right of Claimant to Bring Suit.**

If a claim under **Section 8.1 [Right to Indemnification]** or 8.2 of this Article is not paid in full by the corporation within 30 days after a written claim has been received by the corporation, the claimant may at any time thereafter bring suit against the corporation to recover the unpaid amount of the claim and, if successful in whole or in part, the claimant shall be entitled to be paid also the expense (including attorneys' fees) of prosecuting such claim. The burden of proving such a defense shall be on the corporation. Neither the failure of the corporation (including its Board of Directors, independent legal counsel, or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper under the circumstances because they have met the applicable standard of conduct set forth in the Delaware General Corporation Law, nor an actual determination by the corporation (including its Board of Directors, independent legal counsel, or its stockholders) that the claimant had not met such applicable standard of conduct, shall be a defense to the action or create a presumption that claimant has not met the applicable standard of conduct.

**Section 8.4 Provisions Nonexclusive.**

The rights conferred on any person by this Article shall not be exclusive of any other rights that such person may have or hereafter acquire under any statute, provision of the corporations' Certificate of Incorporation, as amended, or any agreement, vote of stockholders or disinterested directors or otherwise, both as to action in an official capacity and as to action in another capacity while holding such office. To the extent that any provision of the corporation's Certificate of Incorporation, as amended, or any agreement, or vote of the stockholders or disinterested directors is inconsistent with these Amended and Restated Bylaws, the provision, agreement or vote shall take precedence.

**Section 8.5 Authority to Insure.**

The corporation may purchase and maintain insurance to protect itself and any Agent against any Expense, whether or not the corporation would have the power to indemnify the Agent against such Expense under applicable law or the provisions of this Article.

**Section 8.6 Survival of Rights.**

The rights provided by this Article shall continue as to a person who has ceased to be an Agent and shall inure to the benefit of the heirs, executors, and administrators of such a person.

**Section 8.7 Effect of Amendment.**

Any amendment, repeal, or modification of this Article shall not adversely affect any right or protection of any Agent existing at the time of such amendment, repeal, or modification.

**Section 8.8 Subrogation.**

In the event of payment under this Article, the corporation shall be subrogated to the extent of such payment to all of the rights of recovery of the Agent, who shall execute all papers required and shall do everything that may be necessary to secure such rights, including the execution of such documents necessary to enable the corporation effectively to bring suit to enforce such rights.

**Section 8.9 No Duplication of Payments.**

The corporation shall not be liable under this Article to make any payment in connection with any claim made against the Agent to the extent the Agent has otherwise actually received payment (under any insurance policy, agreement, vote, or otherwise) of the amounts otherwise indemnifiable hereunder.

**Section 8.10 Indemnification and Insurance under Israeli Securities Law**

Subject to the Delaware General Corporation Law, the corporation may indemnify and insure any office holder of the corporation from and against any payment which the office holder is obligated to make to an injured party as set forth in Section 52(54)(a)(1)(a) of the Israeli Securities Law, 5278-1968, as amended (“Israeli Securities Law”) and from and against reasonable litigation expenses, including attorneys’ fees, that an office holder may incur in connection with a proceeding under Chapters H’3, H’4 or I’1 of the Israeli Securities Law. Subject to the Delaware General Corporation Law, the corporation is permitted to provide an office holder advanced payments to cover expenses covered under this **Section 8.10 [Indemnification and Insurance under Israeli Securities Law]**.

**ARTICLE IX  
FISCAL YEAR**

The fiscal year of the corporation shall begin on the first day in January of each calendar year and end on the last day of each December following.

**ARTICLE X  
NOTICES**

Whenever, under any provisions of these Amended and Restated Bylaws, notice is required to be given to any stockholder, the same shall be given either (1) in writing, timely and duly deposited in the mail, postage prepaid, and addressed to their last known post office address as shown by the stock record of the corporation or its transfer agent, or (2) by a means of electronic transmission that satisfies the requirements of Section 2.4(e) of these Amended and Restated Bylaws, and has been consented to by the stockholder to whom the notice is given. Any notice required to be given to any director may be given by either of the methods hereinabove stated, except that such notice other than one which is delivered personally, shall be sent to such address or (in the case of electronic communication) such e-mail address, facsimile telephone number or other form of electronic address as such director shall have filed in writing or by electronic communication with the Secretary of the corporation, or, in the absence of such filing, to the last known post office address of such director. If no address of a stockholder or director

be known, such notice may be sent to the principal office of the corporation. An affidavit of mailing, executed by a duly authorized and competent employee of the corporation or its transfer agent appointed with respect to the class of stock affected, specifying the name and address or the names and addresses of the stockholder or stockholders, director or directors, to whom any such notice or notices was or were given, and the time and method of giving the same, shall be conclusive evidence of the statements therein contained. All notices given by mail, as above provided, shall be deemed to have been given as at the time of mailing and all notices given by means of electronic transmission shall be deemed to have been given as at the sending time recorded by the electronic transmission equipment operator transmitting the same. It shall not be necessary that the same method of giving notice be employed in respect of all directors, but one permissible method may be employed in respect of any one or more, and any other permissible method or methods may be employed in respect of any other or others. The period or limitation of time within which any stockholder may exercise any option or right, or enjoy any privilege or benefit, or be required to act, or within which any director may exercise any power or right, or enjoy any privilege, pursuant to any notice sent to them in the manner above provided, shall not be affected or extended in any manner by the failure of such a stockholder or such director to receive such notice. Whenever any notice is required to be given under the provisions of the statutes or of the corporation's Certificate of Incorporation, as amended, or of these Amended and Restated Bylaws, a waiver thereof in writing signed by the person or persons entitled to said notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent thereto. In the event that the action taken by the corporation is such as to require the filing of a certificate under any provision of the Delaware General Corporation Law, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

#### **ARTICLE XI AMENDMENTS**

The Board of Directors shall have the authority to repeal, alter or amend these Amended and Restated Bylaws or adopt new Bylaws (including, without limitation, the amendment of any Bylaws setting forth the number of directors who shall constitute the whole Board of Directors) by unanimous written consent or at any annual, regular, or special meeting by the affirmative vote of a majority of the whole number of directors, subject to the power of the stockholders to change or repeal such Bylaws and provided that the Board of Directors shall not make or alter any Bylaws fixing the qualifications, classifications or term of office of directors.

#### **ARTICLE XII EXCLUSIVE FORUM**

Unless the corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, stockholder, officer or other employee of the corporation to the corporation or the corporation's stockholders, (iii) any action

arising pursuant to any provision of the Delaware General Corporation Law or the corporation's Certificate of Incorporation or these Amended and Restated Bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court, or for which such court does not have subject matter jurisdiction.

Unless the corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, against any person in connection with any offering of the corporation's securities, including, without limitation and for the avoidance of doubt, any auditor, underwriter, expert, control person or other defendant.

Any person or entity purchasing, holding or otherwise acquiring any interest in any security of the corporation shall be deemed to have notice of and consented to the provisions of this **Article XII /EXCLUSIVE FORUM/**. This provision shall be enforceable by any party to a complaint covered by the provisions of this **Article XII /EXCLUSIVE FORUM/**. For the avoidance of doubt, nothing contained in this **Article XII /EXCLUSIVE FORUM/** shall apply to any action brought to enforce a duty or liability created by the Exchange Act or any successor thereto.

## CERTIFICATION

I, Dror Bashan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protalix BioTherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2025

/s/ Dror Bashan

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Dror Bashan

President and Chief Executive Officer

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## CERTIFICATION

I, Eyal Rubin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Protalix BioTherapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 9, 2025

/s/ Eyal Rubin

Eyal Rubin

Sr. Vice President & Chief Financial Officer,  
Treasurer

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## PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 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: May 9, 2025

/s/ Dror Bashan

Dror Bashan

President and Chief Executive Officer

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## PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the “Company”) on Form 10-Q for the period ended March 31, 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: May 9, 2025

/s/ Eyal Rubin

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Eyal Rubin

Senior Vice President and Chief Financial Officer

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