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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from _____ to_____

001-33357
(Commission file number)

PROTALIX BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

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

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

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

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

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

On November 1, 2026, approximately 84,318,923 shares of the Registrant's common stock, $0.001 par value, were outstanding.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 22,035	$ 14,680
Short-term bank deposits	26,503	15,593
Restricted deposit	729	702
Accounts receivable	13,913	8,840
Other assets	1,395	1,129
Inventories	34,297	25,729
Total current assets	$ 98,872	$ 66,673
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ -	$ 578
Property and equipment, net	5,769	4,879
R&D grant receivable	3,030	-
Deferred income tax asset	2,304	2,516
Operating lease right of use assets	8,267	7,700
Total assets	$ 118,242	$ 82,346
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,779	$ 5,259
Other	23,769	19,875
Operating lease liabilities	1,685	1,384
Total current liabilities	$ 30,233	$ 26,518
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ -	$ 661
Operating lease liabilities	7,460	6,937
Total long-term liabilities	$ 7,460	$ 7,598
Total liabilities	$ 37,693	$ 34,116
COMMITMENTS		
STOCKHOLDERS' EQUITY	80,549	48,230
Total liabilities and stockholders' equity	$ 118,242	$ 82,346

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

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

	Nine Months Ended		Three Months Ended	
	September 30, 2026	September 30, 2025	September 30, 2026	September 30, 2025
REVENUES FROM SELLING GOODS	$ 49,081	$ 43,108	$ 21,834	$ 17,673
REVENUES FROM LICENSE AND R&D SERVICES	26,490	514	91	178
TOTAL REVENUE	75,571	43,622	21,925	17,851
COST OF REVENUES	(19,765)	(22,374)	(7,876)	(8,324)
RESEARCH AND DEVELOPMENT EXPENSES, NET	(16,700)	(13,934)	(6,923)	(4,467)
SELLING, GENERAL, AND ADMINISTRATIVE EXPENSES	(9,241)	(8,156)	(3,079)	(2,929)
OPERATING INCOME (LOSS)	29,865	(842)	4,047	2,131
FINANCIAL EXPENSES	(441)	(808)	(24)	(180)
FINANCIAL INCOME	1,199	818	599	288
FINANCIAL INCOME, NET	758	10	575	108
INCOME (LOSS) BEFORE TAXES ON INCOME	30,623	(832)	4,622	2,239
TAXES ON INCOME (TAX BENEFIT)	4,568	268	661	(116)
NET INCOME (LOSS)	$ 26,055	$ (1,100)	$ 3,961	$ 2,355
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ 0.33	$ (0.01)	$ 0.05	$ 0.03
DILUTED	$ 0.31	$ (0.01)	$ 0.05	$ 0.03
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	80,077,803	78,225,112	80,455,731	79,281,685
DILUTED	83,000,983	78,225,112	83,586,774	80,814,564

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

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

	Common Stock (1)	Common Stock	Additional Paid-In Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
Balance at January 1, 2025	**75,850,275**	**$ 76**	**$ 421,528**	**$ (378,393)**	**$ 43,211**
Changes during the nine-month period ended September 30, 2025:					
Issuance of common stock under the Sales Agreement, net	2,775,215	3	6,809		6,812
Share-based compensation related to stock options			1,004		1,004
Share-based compensation related to restricted stock awards	559,210	*	561		561
Exercise of warrants and options	1,156,625	1	2,419		2,420
Net loss for the period				(1,100)	(1,100)
Balance at September 30, 2025	**80,341,325**	**$ 80**	**$ 432,321**	**$ (379,493)**	**$ 52,908**
Balance at January 1, 2026	**80,425,981**	**$ 80**	**$ 433,147**	**$ (384,997)**	**$ 48,230**
Changes during the nine-month period ended September 30, 2026:					
Issuance of common stock under the Sales Agreement, net	1,613,992	1	4,209		4,210
Share-based compensation related to stock options			999		999
Share-based compensation related to restricted stock awards			532		532
Exercise of options	453,296	1	522		523
Net income for the period				26,055	26,055
Balance at September 30, 2026	**82,493,269**	**$ 82**	**$ 439,409**	**$ (358,942)**	**$ 80,549**
Balance at June 30, 2025	**79,732,115**	**$ 80**	**$ 431,671**	**$ (381,848)**	**$ 49,903**
Changes during the three-month period ended September 30, 2025:					
Share-based compensation related to stock options			405		405
Share-based compensation related to restricted stock awards	559,210	*	193		193
Exercise of options	50,000	*	52		52
Net income for the period				2,355	2,355
Balance at September 30, 2025	**80,341,325**	**$ 80**	**$ 432,321**	**$ (379,493)**	**$ 52,908**
Balance at June 30, 2026	**80,571,642**	**$ 81**	**$ 434,226**	**$ (362,903)**	**$ 71,404**
Changes during the three-month period ended September 30, 2026:					
Issuance of common stock under the Sales Agreement, net	1,613,992	1	4,209		4,210
Share-based compensation related to stock options			367		367
Share-based compensation related to restricted stock awards			234		234
Exercise of options	307,635	*	373		373
Net income for the period				3,961	3,961
Balance at September 30, 2026	**82,493,269**	**$ 82**	**$ 439,409**	**$ (358,942)**	**$ 80,549**

* Represents an amount less than $1.

(1) Common stock, $0.001 par value; Authorized – as of September 30, 2026 and December 31, 2025 – 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)

	Nine Months Ended	
	September 30, 2026	September 30, 2025
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 26,055	$ (1,100)
Adjustments required to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Share-based compensation	1,531	1,565
Depreciation	1,231	1,078
Financial expenses, net	192	136
Changes in accrued liability for employee rights upon retirement	(59)	14
Changes in deferred income tax asset	212	177
Gain on amounts funded in respect of employee rights upon retirement	-	(18)
Changes in operating assets and liabilities:		
Increase in accounts receivable-trade and other assets	(5,369)	(11,768)
Changes in operating lease right of use assets, net	138	(62)
Increase in inventories	(8,568)	(12)
Increase in R&D grant receivable	(2,972)	-
Increase (decrease) in accounts payable and accruals	3,138	(4,033)
Net cash provided by (used in) operating activities	$ 15,529	$ (14,023)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in bank deposits	$ (24,065)	$ -
Short-term deposit withdrawal	13,000	-
Purchase of property and equipment	(2,091)	(1,235)
Amounts funded in respect of employee rights upon retirement, net	(40)	(19)
Increase in restricted deposit	(27)	-
Net cash used in investing activities	$ (13,223)	$ (1,254)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock under the Sales Agreement, net	$ 4,210	$ 6,812
Exercise of warrants and options	523	2,368
Net cash provided by financing activities	$ 4,733	$ 9,180
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	$ 316	$ (16)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	7,355	(6,113)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD	14,680	19,760
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 22,035	$ 13,647

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

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

	Nine Months Ended	
	September 30, 2026	**September 30, 2025**
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:		
Purchase of property and equipment	$ 399	$ 230
Exercise of options		$ 52
Operating lease right of use assets obtained in exchange for new operating lease liabilities	$ 1,122	$ 3,104
Settlement of liability for employee rights upon retirement through transfer of the related funds	$ 648	
SUPPLEMENTARY DISCLOSURE ON CASH FLOWS		
Tax paid	$ 4,371	$ 1,182
Interest received	$ 1,005	$ 258

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. and its wholly-owned subsidiary, Protalix Ltd. (collectively, the "Company"), are commercial stage biopharmaceutical companies focused on the discovery, development, production, and commercialization of innovative therapeutics for rare diseases with significant unmet needs. ProCellEx®, the Company's proprietary plant cell-based protein expression system ("ProCellEx"), represents a new method for developing recombinant proteins in an industrial-scale manner.

The Company's commercial product portfolio consists of two enzyme replacement therapies (ERTs):

- Elelyso® (taliglucerase alfa) for the treatment of adult patients and children four years of age and older with Gaucher disease. This product is approved in the United States, Brazil, and Israel, as well as many other jurisdictions.

- Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease. This product is approved in the United States, the European Union, and other jurisdictions with a 1 mg/kg every-two-weeks (E2W) dosage. In March 2026, Elfabrio was approved for a 2 mg/kg every-four-weeks (E4W) dosage in the European Union. Subsequently, the E4W dosage was approved in the UK and other jurisdictions.

On March 31, 2026, following the approval of the E4W dosing regimen for Elfabrio in the EU, the Company received a $25.0 million milestone payment from its commercialization partner for Elfabrio, Chiesi Farmaceutici S.p.A. ("Chiesi").

In addition, the Company's product pipeline currently includes, among other candidates:

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

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

PRX-115 is currently the subject of a Phase 2 clinical trial for the potential treatment of uncontrolled gout (the "RELEASE study").

The Company is committed to leveraging its record of success as the Company develops treatments for rare and orphan diseases. In addition, the Company is continuously further developing and enhancing 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. The Company currently intends to focus on treatments that will address both genetic and non-genetic diseases. The Company plans 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. Consistent with its strategy, 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.

Because the Company's operations are conducted in the State of Israel, the Company's business and operations face risks related to the military, economic, political, and geopolitical conditions in Israel. Since October 2023, Israel has suffered from missile and other similar attacks and has been engaged in military activity on a number of fronts, including with the Hamas and other terrorist groups in the Gaza Strip, with Hezbollah in Lebanon, in Iran, with the Houthis terrorist group that controls parts of Yemen, and others, and both civilian and military targets in Israel have been attacked. In addition, Israel and the U.S. have conducted strikes against Iranian military and nuclear infrastructure which involved Iranian counterattacks as well as Hezbollah attacks on Israel. These situations remain volatile, with the potential for escalation at

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

any time. The Company's facilities are deemed an "essential enterprise," which means it operates or can be operated for the purposes of state defense or public security or for the maintenance of essential supplies or services, allowing the Company to maintain operations during emergencies. The Company has elected to store manufactured drug substance in multiple locations, both within and outside of Israel, to mitigate the risk of loss. It is currently not possible to predict the duration or severity of the above conflicts or the effects of such conflicts, or any of them, on the Company's operations. As of the issuance of these financial statements, the impacts of the military actions described above have not had a material adverse effect on the Company's business, results of operations, and financial condition.

The Company expects to continue to incur significant expenditures in the near future due to research and development efforts with respect to its product candidates. The Company believes that its cash and cash equivalents and short-term bank deposits are sufficient to satisfy the Company's capital needs for at least 12 months from the date that these financial statements are issued.

b. Basis of presentation

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

These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements in the Annual Report on Form 10-K for the year ended December 31, 2025, filed by the Company with the U.S. Securities and Exchange Commission (the "Commission") on March 18, 2026. The comparative balance sheet at December 31, 2025 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, 2025.

c. Net earnings (loss) per share

Basic earnings (loss) per share is calculated by dividing net income (loss) by the weighted average number of shares of common stock, par value $0.001 per share, outstanding for each period.

In computing diluted earnings per share, basic earnings per share are adjusted to take into account the potential dilution that could occur upon: (i) the exercise of options, non-vested restricted stock, and non-vested restricted stock units granted under employee stock compensation plans using the treasury stock method; and (ii) the exercise of warrants using the treasury stock method.

d. New accounting pronouncements

Recently issued accounting pronouncements, not yet adopted

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)

In December 2025, the FASB issued ASU 2025-10 "Government Grants (Topic 832)" to establish authoritative guidance on the accounting for government grants received by business entities. This update is effective beginning with the Company's 2029 fiscal year annual reporting period, with early adoption permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

In December 2025, the FASB issued ASU 2025-11 to amend the guidance in "Interim Reporting" (Topic 270). The update provides clarifications intended to improve the consistency and usability of interim disclosure requirements, including a comprehensive listing of required interim disclosures and a new disclosure principle for reporting material events occurring after the most recent annual period. The amendments do not change the underlying objectives of interim reporting but are designed to enhance clarity in application. The ASU is effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years. The Company is currently evaluating the effects that ASU 2025-11 will have on its interim consolidated financial statements and related disclosures.

NOTE 2 - INVENTORIES

Inventories at September 30, 2026 and December 31, 2025 consisted of the following:

(U.S. dollars in thousands)	September 30, 2026	December 31, 2025
Raw materials	$ 6,396	$ 5,980
Work in progress	7,093	9,375
Finished goods	20,808	10,374
Total inventory	$ 34,297	$ 25,729

NOTE 3 – LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT

Prior to the three months ended June 30, 2026, Protalix Ltd., the Company's Israeli subsidiary, was required in certain circumstances to make a severance payment upon retirement of certain employees. The Company recorded the liability resulting from this obligation on its balance sheets under "Liability for employee rights upon retirement." The Company funded this liability, in part, through the purchase of insurance policies or by the establishment of pension funds, and the amounts so funded were recorded in the Company's balance sheets under "Funds in respect of employee rights upon retirement." Prior to June 30, 2026, the Company amended its agreements with the relevant employees to be consistent with the Company's agreements with the remainder of its employees. Giving effect to such amendments, the Company makes deposits to certain insurance companies or pension funds for accounts controlled by each applicable employee in order to secure the employee's rights upon retirement in lieu of severance. Accordingly, the Company no longer has any remaining funds or liabilities for employee rights upon retirement recognized in its balance sheet and has no subsequent liabilities for severance. The liability accrued and the amounts funded are not recorded in the Company's balance sheets as the amounts funded are not under the Company's control or management, and the liability has been irrevocably transferred to the applicable insurance companies or pension funds.

NOTE 4 – 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.

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

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 5 – STOCK TRANSACTIONS

a. During the nine months ended September 30, 2026, the Company issued, in the aggregate, 453,296 shares of common stock in connection with the exercise of options to purchase 453,296 shares of common stock by certain current and former employees of the Company. The Company received cash proceeds equal to $0.5 million in connection with such exercises.

b. During the three months ended September 30, 2026, the Company sold, in the aggregate, 1,613,992 shares of common stock under that certain At The Market Offering Agreement dated February 27, 2023 and amended on March 17, 2025 (as may be amended from time to time, the "Sales Agreement") between the Company and H.C. Wainwright & Co., LLC, as the Company's sales agent (the "Agent"). The Company generated gross proceeds equal to approximately $4.3 million in connection with such sales (issuance costs were $0.1 million).

c. During the three months ended September 30, 2026, the Company granted, with the approval of the Company's Board of Directors, 10-year options to purchase 1,317,750 shares of common stock, in the aggregate, to certain of the Company's officers, directors, other employees and a consultant under the Company's Amended and Restated 2006 Stock Incentive Plan, as amended (the "Plan"). The options generally vest over a three-year period in 12 equal quarterly increments. Vesting of the options granted to executive officers is subject to automatic acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan, and are subject to certain other terms and conditions. The Company estimated the aggregate fair value of the options on the date of grant using the Black-Scholes option-pricing model to be approximately $2.2 million using the following assumptions (weighted average): stock price equal to $2.59, exercise price equal to $2.59, dividend yield of 0%, expected volatility of 71%, risk-free interest rate of 4.6% and expected life in years, 5.75.

d. During the three months ended September 30, 2026, the Company granted, with the approval of the Company's Board of Directors, 702,925 restricted stock units ("RSUs"), in the aggregate, to certain of the Company's officers, directors, and other employees under the Plan. The RSUs generally vest over a three-year period in 12 equal quarterly increments. Vesting of RSUs granted to executive officers is subject to automatic acceleration in full upon a Corporate Transaction or a Change in Control, as those terms are defined in the Plan, and are subject to certain other terms and conditions. The Company estimated the aggregate fair value of the RSUs on the date of grant to be approximately $1.8 million, based on the closing price of the common stock on the date of grant.

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

NOTE 6 – EARNINGS (LOSS) PER SHARE

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

(In thousands, except share data)	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025
Numerator:				
Net income (loss) for basic and diluted calculation	$ 26,055	$ (1,100)	$ 3,961	$ 2,355
Denominator:				
Weighted average shares of common stock outstanding for basic calculation	80,077,803	78,225,112	80,455,731	79,281,685
Weighted average dilutive effect of stock options and unvested restricted stock	2,923,180		3,131,043	1,532,879
Weighted average shares of common stock outstanding for diluted calculation	83,000,983	78,225,112	83,586,774	80,814,564

Diluted earnings per share do not include 1,765,721 and 2,088,077 shares of common stock underlying outstanding stock options and restricted stock units for the nine and three months ended September 30, 2026, respectively, because the effect would be anti-dilutive.

Diluted earnings (loss) per share does not include 11,288,007 shares of common stock underlying outstanding stock options, unvested shares of restricted stock, and warrants for the nine months ended September 30, 2025, and 3,745,682 shares of common stock underlying outstanding stock options and unvested shares of restricted stock for the three months ended September 30, 2025, because the effect would be anti-dilutive.

NOTE 7 – TAXES ON INCOME

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

(U.S. dollars in thousands)	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025
Current taxes on income - U.S. (federal)	$ 4,356	$ 91	$ 590	$ (175)
Deferred taxes on income - U.S. (federal)	212	177	$ 71	$ 59
Total taxes on income	$ 4,568	$ 268	$ 661	$ (116)

On July 4, 2025, tax reform legislation was enacted in the United States through the passage of H.R.1, The One Big Beautiful Bill Act, which includes significant corporate tax changes, including a restoration of the current deductibility for domestic research expenditures beginning in 2025, with transition options for previously capitalized amounts.

b. On March 31, 2026, the Israeli Knesset enacted the "Law for the Encouragement and Incentivization of Research and Development, 2026" (the "R&D Law"). The R&D Law introduces a refundable tax credit regime calculated as a percentage of qualifying research and development expenditures incurred in Israel (with respect to clinical trials, expenses incurred outside of Israel may, under certain conditions, also qualify), effective from tax year 2026. Subject to certain conditions, eligible companies may apply the credit against Israeli income tax liabilities or the Israeli qualified domestic minimum top-up tax, or, alternatively, to receive a government grant if the credit is not utilized or if the eligible company chooses irrevocably to receive a grant instead of the credit.

The R&D Law requires income from a "Preferred Enterprise" or a "Preferred Technological Enterprise" in order to be eligible for the tax credit, and does not include reference to the historic "Approved Enterprise" track.

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

Following analysis, and after considering, inter alia, (i) the existing tax regime in Israel, including the benefits described above, (ii) the Company's existing net operating loss carryforwards ("NOLs"), (iii) the ability to apply for additional governmental grants for capital investments, (iv) the short-, medium- and long-term benefits as compared with the longer-term benefit available under the Company's current structure, and (v) the 7.5% flat tax rate applicable to "Preferred Technological Income" of a "Preferred Technological Enterprise" ("PTE"), the Company elected to waive its "Approved Enterprise" status and to have the Law for the Encouragement of Capital Investments, 1959, as amended, apply to it under the PTE benefit track. As a result, the Company is eligible to, and intends to, file for grants under the R&D Law (as noted above, the R&D Law includes an option pursuant to which a qualifying company entitled to a tax credit that has not utilized such credit by the tax year ending three years following the year in which the related R&D activity was performed, or if the Company chooses irrevocably, to receive the full amount of the unused credit as a grant payment instead of the credit).

Government grants and refundable tax credits, such as those provided under the recently enacted R&D Law, are recognized as a reduction of the related expense when there is reasonable assurance that the Company will comply with the required conditions and that the incentive will be received. The R&D grant asset is recognized on a discounted basis. For the nine and three months ended September 30, 2026, the Company recorded $3.1 million and $1.0 million, respectively, as a reduction of research and development expenses.

c. On April 2, 2026, the President of the United States issued Proclamation 11020 under Section 232 of the U.S. Trade Expansion Act of 1962 imposing tariffs on imports of certain patented pharmaceutical products and their active pharmaceutical ingredients, including their key starting materials. The tariffs took effect on September 29, 2026 for products of companies that are not listed in Annex III to Proclamation 11020. Different rates apply to patented pharmaceutical products and associated ingredients from certain jurisdictions, from companies with U.S. Department of Commerce-approved onshoring agreements, and from companies with "most-favored-nation" pricing agreements with the U.S. Department of Health and Human Services. There are also exceptions for certain specialty drugs and products imported solely for clinical trials or research and development. The Company is actively pursuing measures to mitigate or eliminate the adverse effect of the applicable tariffs. Increased tariffs may impact the Company's ability to commercialize its current and future products under development in the U.S. The extent of the impact that such tariffs will have on the Company specifically, or on the U.S. market and global economy generally, is uncertain and unpredictable, and could have a material adverse effect on the Company's business, results of operations, and financial condition.

NOTE 8 – 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 based on net income (losses).

b. Segment information:

	Nine Months Ended September 30,		Three Months Ended September 30,	
(U.S. dollars in thousands)	2026	2025	2026	2025
Revenues from customers	$ 75,571	$ 43,622	$ 21,925	$ 17,851
Less:				
Employee salaries and related expenses	21,738	16,502	7,386	5,853
Sub-contractors expense	14,443	9,348	6,103	1,886
Interest expense	-	-	-	-
Interest income	(911)	(818)	(366)	(288)
Depreciation	1,231	1,078	424	372
R&D grant	(3,089)		(989)	
Other segment expenses, net*	11,536	18,344	4,745	7,789
Income (loss) before taxes on income	30,623	(832)	4,622	2,239
Taxes on income (tax benefit)	4,568	268	661	(116)
Segment net income (loss)	$ 26,055	$ (1,100)	$ 3,961	$ 2,355

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

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

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

(U.S. dollars in thousands)	Nine Months Ended September 30, 2026	Nine Months Ended September 30, 2025	Three Months Ended September 30, 2026	Three Months Ended September 30, 2025
Gaucher disease:				
Pfizer (Ireland)	$ 10,062	$ 15,431	$ 4,331	$ 2,805
Fiocruz (Brazil)	$ 8,333	$ 9,121	$ 4,365	$ 6,105
Fabry disease:				
Chiesi (Italy)	$ 30,686	$ 18,556	$ 13,138	$ 8,763
Total revenues from selling goods	$ 49,081	$ 43,108	$ 21,834	$ 17,673
Revenues from license and R&D services	$ 26,490	$ 514	$ 91	$ 178

d. Long lived assets are located in Israel.

NOTE 9 – SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION

a. Balance sheets:

(U.S. dollars in thousands)	September 30, 2026	December 31, 2025
Accounts payable and accruals – other:		
Payroll and related expenses	$ 2,044	$ 1,629
Provision for vacation	2,699	2,309
Accrued expenses	12,004	9,790
Royalties payable	655	799
Income tax payable	2,936	2,950
Payable to customer	3,032	2,029
Property and equipment suppliers	399	369
	$ 23,769	$ 19,875

b. Statements of Operations:

(U.S. dollars in thousands)	Nine Months Ended September 30,		Three Months Ended September 30,	
Research and development expenses:	2026	2025	2026	2025
Employee salaries and related expenses	$ 8,872	$ 6,528	$ 3,049	$ 2,588
Subcontractor-related expenses	7,363	4,316	3,788	504
Materials-related expenses	1,147	880	414	454
Depreciation	402	388	138	157
Other expenses	2,005	1,822	523	764
Less - R&D grant	(3,089)	—	(989)	—
	$ 16,700	$ 13,934	$ 6,923	$ 4,467

NOTE 10 – SUBSEQUENT EVENTS

a. Since the end of the quarter ended September 30, 2026, the Company collected approximately $9.3 million from sales to Chiesi and approximately $3.0 million from sales to Fiocruz (Brazil).

b. Since the end of the quarter ended September 30, 2026, the Company sold, in the aggregate, 1,798,325 shares of common stock under the Sales Agreement and the Company generated gross proceeds equal to approximately $4.9 million in connection with such sales (issuance costs were $0.1 million).

PROTALIX BIOTHERAPEUTICS, INC.
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(Unaudited)

c. Since the end of the quarter ended September 30, 2026, the Company issued, in the aggregate, 27,329 shares of common stock in connection with exercises of options to purchase 27,329 shares of common stock by certain current and former employees of the Company. The Company received cash proceeds equal to approximately $50,000 in connection with such exercises.

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, 2025. Some of the information contained in this discussion and analysis, particularly with respect to our plans and strategy for our business and related financing, includes forward-looking statements within the meanings of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding expectations, beliefs, intentions or strategies for the future. When used in this report, the terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would," and words or phrases of similar import, as they relate to our company, our subsidiary or our management, are intended to identify forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance, and we undertake no obligation to update or revise, nor do we have a policy of updating or revising, any forward-looking statement to reflect events or circumstances after the date on which the statement is made or to reflect the occurrence of unanticipated events, except as may be required under applicable law. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements as a result of several factors, including those set forth in this Quarterly Report on Form 10-Q.

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

- risks related to the commercialization of Elfabrio® (pegunigalsidase alfa-iwxj), our approved product for the treatment of adult patients with Fabry disease;

- risks relating to Elfabrio's market acceptance, competition, reimbursement, and regulatory actions, including as a result of the boxed warning contained in the approval received from the U.S. Food and Drug Administration, or FDA, for the product;

- risks associated with global conditions and developments such as new or increased tariffs, treaties, trade policies, taxes, and other limitations on cross-border operations, which may adversely impact our business, results of operations, and financial condition;

- 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; and/or inability to monitor patients adequately during or after treatment;

- the risk that the results of the clinical trials of our product candidates 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;

- the possible disruption of our operations due to the regional conflict in Iran and the military actions between Israel and Iran, the Hamas terrorist organization located in the Gaza Strip, Hezbollah, the Houthis terrorist group that controls parts of Yemen, and others, 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 increased regional conflict;

- 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 other global conditions and developments such as new or changed trade restrictions, supply chain challenges, the inflationary environment, and tight labor market, and instability in the banking industry, which may adversely impact our business, results of operations, and financial condition, and our 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;

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

- risks related to the amount and sufficiency of our cash, 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 the Supply and Technology Transfer Agreement that we entered into with Fiocruz in June 2013, or the Brazil Agreement, which may have a material adverse effect on us and may result in our 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

Protalix BioTherapeutics, Inc. and its wholly-owned subsidiary, Protalix Ltd., are commercial stage biopharmaceutical companies focused on the discovery, development, production, and commercialization of innovative therapeutics for rare diseases with significant unmet needs. ProCellEx®, our proprietary plant cell-based protein expression system, represents a new method for developing recombinant proteins in an industrial-scale manner.

Currently, our commercial products are both enzyme replacement therapies (ERTs):

- Elelyso® (taliglucerase alfa) for the treatment of adult patients and children four years of age and older with Gaucher disease. This product is approved in the United States, Brazil, and Israel, as well as many other jurisdictions.

- Elfabrio® (pegunigalsidase alfa) for the treatment of adult patients with a confirmed diagnosis of Fabry disease. This product is approved in the United States, the European Union, and other jurisdictions with a 1 mg/kg every-two-weeks (E2W) dosage. Additionally, in March 2026, Elfabrio was approved for a 2 mg/kg every-four-weeks (E4W) dosage in the European Union. Subsequently, the E4W dosage was approved in the UK and other jurisdictions.

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 are likely to 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.

Our product pipeline currently includes, among other candidates:

- PRX-115, a recombinant PEGylated uricase (urate oxidase) – a chemically modified enzyme to treat uncontrolled gout; and

- PRX-119, a PEGylated recombinant human DNase I product candidate for long and customized systemic circulation in the bloodstream for NETs-related diseases (neutrophil extracellular traps).

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

Given ongoing military actions in the Middle East, and the missile and other strikes within Israel, we have elected to store manufactured drug substance in multiple locations, both within and outside of Israel, to mitigate the risk of loss. Our facilities are deemed an “essential enterprise” which means they operate or can be operated for the purposes of state defense or public security or for the maintenance of essential supplies or services, allowing us to maintain operations during emergencies. To date, the impact of the military actions have not had a material adverse effect on our operations.

Commercialization of Approved Products

Elelyso – Pfizer

We licensed to Pfizer the global rights to market and sell Elelyso in all markets, excluding Brazil, pursuant to an amended and restated exclusive license and supply agreement, or the Amended Pfizer Agreement. Pursuant to the Amended Pfizer Agreement, we agreed to sell drug substance to Pfizer for the production of Elelyso for a fixed cost, subject to certain terms and conditions, through 2030. 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.

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

Alfataliglicerase – Fundação Oswaldo Cruz (Fiocruz)

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

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

Our sales of BioManguinhos alfataliglicerase to Fiocruz are made at a fixed price directly to Fiocruz which maintains product in inventory, and we recognize revenue from those sales upon delivery. The timing of such sales does not directly reflect patient demand and, on a period-to-period basis, there may be variations in the orders placed by Fiocruz resulting in variability in our period-to-period results. There may be periods during which no orders are placed by Fiocruz, whether as a result of inventory de-stocking or other factors.

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

Elfabrio is commercialized worldwide by Chiesi under two exclusive global licensing and supply agreements; the Exclusive License and Supply Agreement dated as of October 17, 2017, by and between Protalix Ltd. and Chiesi, or the Chiesi Ex-US Agreement, and the Exclusive License and Supply Agreement dated as of July 23, 2018, by and between Protalix Ltd. and Chiesi, or the Chiesi US Agreement. The Chiesi Ex-US Agreement and the Chiesi US Agreement are referred to herein collectively as the Chiesi Agreements. Under the Chiesi Ex-US Agreement, we granted to Chiesi an exclusive license for all markets outside of the United States to commercialize pegunigalsidase alfa. At execution of the Chiesi Ex-US Agreement, Chiesi made an upfront, non-refundable, non-creditable payment to Protalix Ltd. of $25.0 million, followed by additional payments of $25.0 million to cover development costs in the aggregate. Following the approval of the E4W dosage by the EMA in 2026, we received a milestone payment equal to $25.0 million. Protalix Ltd. currently remains eligible to receive additional payments of up to a maximum of $270.0 million, in the aggregate, subject to the satisfaction of certain regulatory and commercial milestones. Protalix Ltd. agreed to manufacture all of the pegunigalsidase alfa needed for all purposes under the agreement, subject to certain exceptions, and Chiesi agreed to purchase the pegunigalsidase alfa from Protalix Ltd., subject to certain terms and conditions. Chiesi is required to make payments to Protalix Ltd. ranging from 15% to 35% of its net sales under the Chiesi Ex-US Agreement, depending on the amount of annual sales, subject to certain terms and conditions, as consideration for product supply. The Chiesi Ex-US Agreement shall remain in effect until the later of (i) the expiration of the last enforceable Protalix patent right thereunder or (ii) the 15th anniversary of the launch of sales of pegunigalsidase alfa on a country-by-country basis, subject to certain terms and conditions, unless earlier terminated in accordance with the terms and conditions thereof.

Under the Chiesi US Agreement we granted to Chiesi the exclusive license to develop and commercialize pegunigalsidase alfa in the United States. Protalix Ltd. received from Chiesi an upfront, non-refundable, non-creditable payment of $25.0 million and additional payments of $20.0 million to cover development costs. To date, we have received the complete amount of such development costs, and, following the approval of Elfabrio by the FDA, we received a milestone payment equal to $20.0 million. Protalix Ltd. currently remains eligible to receive additional payments of up to a maximum of $740.0 million, in the aggregate, subject to the satisfaction of certain regulatory and commercial milestones. Chiesi is required to make payments to Protalix Ltd. ranging from 15% to 40% of its net sales under the Chiesi US Agreement, depending on the amount of annual sales, subject to certain terms and conditions, as consideration for product supply. The Chiesi US Agreement shall remain in effect until the later of (i) the expiration of the last enforceable Protalix patent right thereunder or (ii) the 15th anniversary of the launch in the U.S., unless earlier terminated in accordance with the terms and conditions thereof.

We manufacture Elfabrio drug substance and, after the fill/finish process is complete, we sell the resulting drug product to Chiesi under both agreements. Operationally, Chiesi conducts its own internal commercial forecasting to guide inventory needs. To date, Chiesi has placed bulk orders for Elfabrio. As a result, the orders we receive from Chiesi may not be timed in relation to Chiesi's pace of patient acquisition and retention. Accordingly, our sales of Elfabrio to Chiesi may not reflect patient demand for Elfabrio as we sell the fulfilled orders to Chiesi's inventory. In addition, on a period-to-period basis, there may be variations in the orders placed by Chiesi resulting in variability in our period-to-period results as we, in turn, recognize revenues from sales of Elfabrio upon delivery of the drug product to Chiesi. There may be periods during which no orders are placed by Chiesi, whether as a result of inventory de-stocking or other factors. We do not anticipate that these Chiesi ordering patterns will change until the demand characteristics for Elfabrio stabilize, the launch of Elfabrio matures and Elfabrio's share of the market for Fabry disease treatment grows both inside the U.S. and outside the U.S.

Intellectual Property

A key element of our overall strategy is to establish a broad portfolio of patents to protect our proprietary technology, proprietary product and product candidates and their methods of use. As of September 30, 2026, we hold a broad portfolio of 15 patent families consisting of approximately 72 patents in Europe, the United States, Israel, and additional countries worldwide, as well as approximately 35 pending patent applications.

Research & Development

We are committed to leveraging our track record of success as we develop treatments for rare and orphan diseases. In addition, we are continuously further developing and enhancing 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. We currently intend that our treatments will address both genetic and non-genetic diseases. We currently intend to use our ProCellEx platform and PEGylation/chemical 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 to expand our pipeline.

In addition, we continuously work on the further development of our ProCellEx plant cell expression technology and bioreactor system.

We are eligible to, and intend to, file for grants under the R&D Law (as noted above, the R&D Law includes an option pursuant to which a qualifying company entitled to a tax credit that has not utilized such credit by the tax year ending three years following the year in which the related R&D activity was performed or if we choose irrevocably, to receive the full amount of the unused credit as a grant payment instead of the credit).

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, 2025.

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

The following table sets forth certain statements of operations data:

	Nine Months Ended September 30,		Three Months Ended September 30,	
(U.S. dollars in thousands)	**2025**	**2026**	**2025**	**2026**
REVENUES FROM SELLING GOODS	43,108	49,081	$ 17,673	$ 21,834
REVENUES FROM LICENSE AND R&D SERVICES	514	26,490	178	91
TOTAL REVENUE	43,622	75,571	17,851	21,925
COST OF REVENUES	(22,374)	(19,765)	(8,324)	(7,876)
RESEARCH AND DEVELOPMENT EXPENSES, NET	(13,934)	(16,700)	(4,467)	(6,923)
SELLING, GENERAL, AND ADMINISTRATIVE EXPENSES	(8,156)	(9,241)	(2,929)	(3,079)
OPERATING INCOME (LOSS)	(842)	29,865	2,131	4,047
FINANCIAL EXPENSES	(808)	(441)	(180)	(24)
FINANCIAL INCOME	818	1,199	288	599
FINANCIAL INCOME, NET	10	758	108	575
INCOME (LOSS) BEFORE TAXES ON INCOME	(832)	30,623	2,239	4,622
TAXES ON INCOME (TAX BENEFIT)	268	4,568	(116)	661
NET INCOME (LOSS)	(1,100)	26,055	2,355	3,961

Three and nine months ended September 30, 2026 compared to the three and nine months ended September 30, 2025

Revenues from Selling Goods

Revenues from selling goods consisted of the following:

	Nine Months Ended September 30,			Three Months Ended September 30,		
(U.S. dollars in thousands)	2025	2026	2026 vs. 2025	2025	2026	2026 vs. 2025
Pfizer	$ 15,431	$ 10,062	$ (5,369)	$ 2,805	$ 4,331	$ 1,526
Fiocruz	9,121	8,333	(788)	6,105	4,365	(1,740)
Chiesi	18,556	30,686	12,130	8,763	13,138	4,375
Total revenues from selling goods	43,108	49,081	5,973	17,673	21,834	4,161

Revenues from selling goods for the three and nine months ended September 30, 2026 reflects an increase of 23.5% and 13.9% compared to the three and nine months ended September 30, 2025, respectively. The total increase in revenues from selling goods for the three and nine months ended September 30, 2026 resulted primarily from an increase in sales to Chiesi. The decrease in sales to Pfizer for the nine months ended September 30, 2026 resulted primarily from Pfizer's purchases to address unexpected manufacturing issues at Pfizer in 2025. The increase in sales to Pfizer and the decrease in sales to Fiocruz (Brazil) for the three months ended September 30, 2026 resulted primarily from the timing of deliveries.

Revenues from License and R&D Services

Revenues from license and R&D services were as follows:

	Nine Months Ended September 30,			Three Months Ended September 30,		
(U.S. dollars in thousands)	2025	2026	2026 vs. 2025	2025	2026	2026 vs. 2025
Revenues from license and R&D services	$ 514	$ 26,490	$ 25,976	$ 178	$ 91	$ (87)

The decrease in revenues from license and R&D services for the three months ended September 30, 2026 compared to the three months ended September 30, 2025 resulted from a decrease in the amount of services provided to Chiesi. The increase in revenues from license and R&D services for the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025 resulted from the $25.0 million milestone we received from Chiesi in connection with the approval of the E4W dosage in the EU in the first quarter of 2026. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. Other than potential regulatory milestone payments that may become payable, we expect to generate minimal revenues from license and R&D services now that we have completed the clinical development of Elfabrio.

Cost of Revenues

Cost of revenues were as follows:

	Nine Months Ended September 30,			Three Months Ended September 30,		
(U.S. dollars in thousands)	2025	2026	2026 vs. 2025	2025	2026	2026 vs. 2025
Cost of revenues	$ 22,374	$ 19,765	$ (2,609)	$ 8,324	$ 7,876	$ (448)

Cost of revenues for the three months ended September 30, 2026 represents a decrease of 5.4% compared to the three months ended September 30, 2025. The decrease resulted primarily from a decrease in sales to Fiocruz (Brazil) which was partially offset by an increase in sales to Chiesi and to Pfizer. Cost of revenues for the nine months ended September 30, 2026 represents a decrease of 11.7% compared to the nine months ended September 30, 2025. The decrease resulted primarily from a decrease in sales to Pfizer and to Fiocruz (Brazil) which was partially offset by an increase in sales to Chiesi.

Research and Development Expenses

Research and development expenses were as follows:

	Nine Months Ended September 30,			Three Months Ended September 30,		
(U.S. dollars in thousands)	2025	2026	2026 vs. 2025	2025	2026	2026 vs. 2025
Salary and related expenses	$ 6,528	$ 8,872	$ 2,344	$ 2,588	$ 3,049	$ 461
Subcontractor-related expenses	4,316	7,363	3,047	504	3,788	3,284
Materials-related expenses	880	1,147	267	454	414	(40)
Other expenses	2,210	2,407	197	921	661	(260)
Less - R&D grant		(3,089)	(3,089)		(989)	(989)
Total research and development expenses	13,934	16,700	2,766	4,467	6,923	2,456

Total increase in research and development expenses for the three months ended September 30, 2026 represents an increase of 55.0% compared to the three months ended September 30, 2025. The increase in research and development expenses resulted primarily from a $3.3 million increase in subcontractor-related expenses mainly related to the RELEASE study which was partially offset by a $1.0 million grant recorded in accordance with the new R&D law as a reduction of research and development expenses. The increase in research and development expenses for the nine months ended September 30, 2026 represents an increase of 19.9% compared to the nine months ended September 30, 2025. The increase resulted primarily from an increase in subcontractor-related expenses mainly related to the RELEASE study and in salary and related expenses, and was partially offset by the $3.1 million grant recorded in accordance with the new Israeli R&D law as a reduction of research and development expenses.

We expect to continue to incur significant, increasing research and development expenses as we progress with the RELEASE study and commence more advanced stages of preclinical and clinical trials for certain of our other product candidates.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses were as follows:

	Nine Months Ended September 30,			Three Months Ended September 30,		
(U.S. dollars in thousands)	2025	2026	2026 vs. 2025	2025	2026	2026 vs. 2025
SG&A expenses	$ 8,156	$ 9,241	$ 1,085	$ 2,929	$ 3,079	$ 150

Selling, general, and administrative expenses for the three and nine months ended September 30, 2026 represents an increase of 5.1% and 13.3% compared to the three and nine months ended September 30, 2025, respectively. The increase resulted primarily from an increase of $0.7 million in salary and related expenses, $0.2 million in selling expenses, and $0.2 million in other expenses for the nine months ended September 30, 2026, and of $0.1 million in professional fees and $0.1 million in salary and related expenses for the three months ended September 30, 2026.

Financial Income, Net

Financial income, net was as follows:

	Nine Months Ended September 30,			Three Months Ended September 30,		
(U.S. dollars in thousands)	2025	2026	2026 vs. 2025	2025	2026	2026 vs. 2025
Financial income, net	$ 10	$ 758	$ 748	$ 108	$ 575	$ 467

The increase in financial income, net for the three and nine months ended September 30, 2026 resulted primarily from exchange rate fluctuations between the U.S. dollar and the New Israel Shekel, and higher interest income.

Income Taxes (Tax Benefit)

Income taxes were as follows:

	Nine Months Ended September 30,			Three Months Ended September 30,		
(U.S. dollars in thousands)	2025	2026	2026 vs. 2025	2025	2026	2026 vs. 2025
Taxes on income	$ 268	$ 4,568	$ 4,300	$ (116)	$ 661	$ 777

We recorded tax expenses of approximately $0.7 million and $4.6 million for the three and nine months ended September 30, 2026, respectively. The tax expenses resulted primarily from taxes on income mainly derived from global intangible low-taxed income (GILTI) resulting primarily from limitations under IRC Section 174 and from the taxes related to our receipt of the $25 million milestone payment in the first quarter of 2026. On July 4, 2025, tax reform legislation was enacted in the United States through the passage of H.R.1, The One Big Beautiful Bill Act, which includes significant corporate tax changes, including a restoration of the current deductibility of domestic research expenditures beginning in 2025 under Section 174A, with transition options for previously capitalized amounts. Foreign research expenditures continue to require capitalization subject to the mandatory 15-year amortization period under existing IRC Section 174. We implemented the permitted transition options.

Liquidity and Capital Resources

Our sources of liquidity include our cash and cash equivalents and short-term bank deposits. At September 30, 2026, we had $48.5 million in cash and cash equivalents and short-term bank deposits. We have primarily financed our operations through sales proceeds, equity and debt financings, business collaborations, and grants funding.

On February 27, 2023, we entered the Sales Agreement with the Agent which provided for the sale, from time to time through the Agent, shares of common stock having an aggregate offering price of up to $20.0 million. On March 17, 2025, the Sales Agreement was amended to increase the aggregate gross sales price of shares of common stock available for offer and sale under the Sales Agreement by $20.0 million. We have no obligation to sell any shares of common stock under the Sales Agreement, and may at any time suspend sales under the Sales Agreement or terminate the Sales Agreement in accordance with its terms. The Agent is entitled to a commission of up to 3.0% of the aggregate gross proceeds from the shares of common stock sold under the Sales Agreement. During the nine months ended September 30, 2025, we sold, in the aggregate, 2,775,215 shares of common stock under the Sales Agreement, generating gross proceeds equal to approximately $7.0 million (issuance costs were $0.2 million). During the nine months ended September 30, 2026, we sold, in the aggregate 1,613,992 shares of common stock under the Sales Agreement generating gross proceeds equal to approximately $4.3 million (issuance costs were $0.1 million). All such sales occurred in the three months ended September 30, 2026. As of September 30, 2026, approximately $11.3 million in shares of common stock remain available to be sold under the Sales Agreement.

During the three months ended March 31, 2025, we issued 908,000 shares of common stock, in the aggregate, 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.

During the nine months ended September 30, 2025 and 2026, we issued 248,625 and 453,296 shares of common stock, respectively, in the aggregate, in connection with the exercise of options to purchase 248,625 and 453,296 shares of common stock by certain of our current and former employees. We received cash proceeds equal to $0.3 million and $0.5 million, respectively, in connection with such exercises.

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

Our cash flows for each of the nine months ended September 30, 2026 and 2025 were as follows:

	Nine Months Ended September 30,		
(U.S. dollars in thousands)	2025	2026	2026 vs. 2025
Net cash provided by (used in) operating activities	$ (14,023)	$ 15,529	$ 29,552
Net cash used in investing activities	$ (1,254)	$ (13,223)	$ (11,969)
Net cash provided by financing activities	$ 9,180	$ 4,733	$ (4,447)

Net cash provided by operations was $15.5 million for the nine months ended September 30, 2026. The net income for the nine months ended September 30, 2026 of $26.1 million was increased by a $3.1 million increase in accounts payable and accruals, $1.5 million in share-based compensation, net and $1.2 million in depreciation and partially offset by $5.4 million increase in accounts receivable-trade and other assets, $8.6 million increase in inventories, and $3.0 million increase in R&D grant.

Net cash used in investing activities was $13.2 million for the nine months ended September 30, 2026 and consisted primarily of $24.1 million investment in bank deposits partially offset by a $13.0 million short-term deposit withdrawal and $2.1 million in the purchase of property and equipment.

Net cash provided by financing activities was $4.7 million for the nine months ended September 30, 2026 and resulted from $4.2 million proceeds from issuance of common stock under the sales agreement, net and $0.5 million from the exercise of stock options.

Net cash used in operations was $14.0 million for the nine months ended September 30, 2025. The net loss for the nine months ended September 30, 2025 of $1.1 million was increased by a $11.8 million increase in accounts receivable-trade and other assets, a $4.0 million decrease in accounts payable and accruals, and was offset by a $1.6 million in share-based compensation and $1.1 million in depreciation.

Net cash used in investing activities for the nine months ended September 30, 2025 was $1.3 million and consisted primarily of the purchase of property and equipment.

Net cash provided by financing activities for the nine months ended September 30, 2025 was $9.2 million and consisted of $6.8 million proceeds from issuance of common stock under the Sales Agreement, net and $2.4 million from the exercise of warrants and options.

Future Funding Requirements

Since our inception, we have incurred significant research and development expenditures which have not been offset by revenues. We have generated operating losses from our continuing operations since our inception except for the years ended December 31, 2023 and 2024, and the reported periods of 2026.

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, in particular those of our RELEASE study, (ii) employee salaries, (iii) payments for rent and operation of our manufacturing facilities, (iv) fees to our consultants and legal advisors, patent advisors and fees for service providers in connection with our research and development efforts, (v) expansion of additional manufacturing space within our current facility and (vi) tax payments. We believe that the funds currently available to us are sufficient to satisfy our capital needs for at least 12 months 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, preclinical development, and clinical trials for our product candidates;
- Chiesi’s progress in commercializing Elfabrio;
- our progress in commercializing BioManguinhos alfataliglicerase in Brazil;
- the timing and outcome of regulatory review of our product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights; and
- the costs associated with any litigation claims.

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

Effects of Currency Fluctuations

Currency fluctuations could affect us through increased or decreased acquisition costs for certain goods and services and salaries expenses. For the nine months ended September 30, 2026 the currency fluctuations resulted in expenses of approximately $0.4 million.

Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as of each of September 30, 2026 and December 31, 2025.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Currency Exchange Risk

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

Approximately 41% of our costs, including salaries, expenses and office expenses, are incurred in NIS. Inflation in Israel may have the effect of increasing the U.S. dollar cost of our operations in Israel. If the U.S. dollar declines in value in relation to the NIS, it will become more expensive for us to fund our operations in Israel. A revaluation of 1% of the NIS will affect our loss before tax by less than 1%. The exchange rate of the U.S. dollar to the NIS, based on exchange rates published by the Bank of Israel, was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,		Year Ended December 31,
	2026	2025	2026	2025	2025
Average rate for period	3.019	3.364	3.030	3.519	3.452
Rate at period-end	3.063	3.306	3.063	3.306	3.190

We engage in, from time to time, 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 volatility in currency exchange rates and inflation.

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-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2026 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, 2025 and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the quarter ended September 30, 2026, none of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as such terms are defined in Item 408 of Regulation S-K).

Item 6. Exhibits

		Incorporated by Reference				
Exhibit Number	Exhibit Description	Form	File Number	Exhibit	Date	Filed or Furnished Herewith
3.1	Certificate of Incorporation of the Company	8-K	001-33357	3.1	April 1, 2016	
3.2	Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	July 1, 2016	
3.3	Second Amendment to Certificate of Incorporation of the Company	Def 14A	001-33357	Appen. A	October 17, 2018	
3.4	Third Amendment to Certificate of Incorporation of the Company	8-K	001-33357	3.1	December 19, 2019	
3.5	Fourth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.5	August 15, 2022	
3.6	Fifth Amendment to Certificate of Incorporation of the Company	10-Q	001-33357	3.6	August 7, 2023	
3.7	Second Amended and Restated Bylaws of the Company	10-Q	001-33357	3.7	May 9, 2025	
4.1†	Form of Restricted Stock Agreement/Notice	8-K	001-33357	4.1	July 18, 2012	
4.2	Description of Capital Stock	10-K	001-33357	4.4	March 18, 2026	
4.3†	Form of Stock Option Agreement (Executives)	10-Q	001-33357	4.8	August 10, 2020	
4.4	Form of Stock Option Agreement (Standard)	10-Q	001-33357	4.9	August 10, 2020	
10.1†	Amended and Restated Protalix BioTherapeutics, Inc. 2006 Stock Incentive Plan	8-K	001-33357	10.1	June 25, 2026	
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					X

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

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

SIGNATURES

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

PROTALIX BIOTHERAPEUTICS, INC.
(Registrant)

Date: November 10, 2026

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

Date: November 10, 2026

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

EXHIBIT 31.1

CERTIFICATION

I, Dror Bashan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2026

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

EXHIBIT 31.2

CERTIFICATION

I, Gilad Mamlok, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 10, 2026

/s/ Gilad Mamlok
Gilad Mamlok
Sr. Vice President & Chief Financial Officer,
Treasurer

EXHIBIT 32.1

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 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: November 10, 2026

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

EXHIBIT 32.2

PROTALIX BIOTHERAPEUTICS, INC.

CERTIFICATION

In connection with the quarterly report of Protalix BioTherapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission (the "Report"), I, Gilad Mamlok, Senior Vice President and Chief Financial Officer of the Company, hereby certify as of the date hereof, solely for the purposes of Title 18, Chapter 63, Section 1350 of the United States Code, that to the best of my knowledge:

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

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

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

Date: November 10, 2026

/s/ Gilad Mamlok
Gilad Mamlok
Senior Vice President and Chief Financial Officer