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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): March 18, 2026

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-33357**	**65-0643773**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2 University Plaza Suite 100 Hackensack, NJ		**07601**
(Address of principal executive offices)		**(Zip Code)**

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

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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. ☐

Item 2.02 Results of Operations and Financial Condition

On March 18, 2026, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended December 31, 2025 and provided a business and clinical update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

Exhibit No.	Description
99.1	Press Release dated March 18, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

Date: March 18, 2026

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports Fiscal Year 2025 Financial and Business Results

Company to host conference call and webcast today at 8:00 a.m. EDT

- The European Commission (EC) approved the 2mg/kg every-4-weeks (E4W) dosing regimen for Elfabrio® in adults living with Fabry disease providing a meaningful reduction in treatment burden without compromising efficacy

- The EC approval triggered the Company's entitlement to a $25.0 million milestone payment from Chiesi, strengthening the Company's cash position and supporting an expected cash balance of approximately $50.0 million by April 2026

- Based on current estimates, management expects total revenues in 2026 to range from approximately $78.0 million to $83.0 million including the $25.0 million payment referenced above

- The Phase 2 clinical trial of PRX-115 is actively enrolling; the Company believes PRX-115 has the potential to be a best-in-class therapy, improving uncontrolled gout patients' compliance and outcomes

- Continued strategic focus on rare renal diseases to build a pipeline through innovation and partnerships

CARMIEL, Israel, March 18, 2026 -- Protalix BioTherapeutics, Inc. (NYSE American:PLX), a biopharmaceutical company focused on the discovery, development, production and commercialization of innovative therapeutics for rare diseases with significant unmet needs, today reported financial results for the fiscal year ended December 31, 2025, and provided a business and clinical update.

"2025 was a year of meaningful progress for Protalix, marked by strong commercial execution with our partners and important advances and strategic direction across our clinical and preclinical pipeline," said Dror Bashan, President and Chief Executive Officer, Protalix BioTherapeutics. "The EC approval of the E4W dosing regimen for Elfabrio in the European Union represents an advancement for patients by reducing treatment burden without compromising efficacy. This milestone strengthens the long-term value of our Fabry franchise. In parallel, we believe the ongoing development of PRX-115 positions us to address the substantial unmet need in uncontrolled gout with a potential best-in-class therapy. We are also sharpening our focus on rare renal diseases with PRX-119 and our RNA-based discovery collaboration with Secarna, leveraging the capabilities of our ProCellEx® platform. As we enter 2026, we remain committed to driving profitable growth, expanding opportunities across our portfolio, and delivering innovative therapies that meaningfully improve the lives of patients with rare diseases."

Recent Business Highlights

Elfabrio for Fabry Disease - E4W regimen provides meaningful reduction in treatment burden in EU

- In March 2026, the European Commission (EC) approved a novel 2mg/kg every-4-weeks (E4W) dosing regimen for Elfabrio in adults with Fabry disease who are stable on an enzyme replacement therapy (ERT).
- This decision followed the positive opinion from the Committee for Medicinal Products for Human Use (CHMP) recommending this additional dosing regimen.
- The E4W regimen provides a potentially meaningful reduction in treatment burden without comprising efficacy, one of the more common unmet needs in Fabry disease, and the 50%

infusion frequency reduction represents a quality of life improvement for Fabry patients in the EU.
- This approval was supported by the BRIGHT study and long--term extension data, which demonstrated that the E4W dosing regimen maintained clinical and renal outcomes in stable patients.
- Further support came from an updated Population Pharmacokinetics (PopPK) model and exposure–response analysis, which leveraged data from multiple clinical studies.
- Elfabrio is now the only ERT approved for E4W dosing to treat Fabry in the EU – strengthening its competitive positioning and potential market share expansion.
- The FDA-approved dosing regimen for Elfabrio in the United States remains 1mg/kg every 2 weeks.

PRX-115 for Uncontrolled Gout – Phase 2 trial actively enrolling

- Actively enrolling, and the first patients have been randomized, in the RELEASE Phase 2 clinical trial of PRX-115 (NCT07280156), a recombinant PEGylated uricase.
- The RELEASE study builds on favorable Phase 1 clinical trial results, where PRX-115 was generally well-tolerated and demonstrated rapid, durable serum urate reduction below target levels across all cohorts.
- PRX-115 is designed as a potential best-in-class, long-acting therapy, with a possible E4W dosing schedule with or without an immunomodulator, or less frequent dosing with an immunomodulator, aiming to improve adherence and durability of response for patients with uncontrolled gout.
- By addressing immunogenicity challenges and enabling more flexible dosing intervals, the Company believes PRX-115 is well-positioned to capture a meaningful share in the uncontrolled gout segment, where even modest penetration represents significant commercial opportunity.
- The Company anticipates top-line results in the second half of 2027.
- The Company recently received an allowance from the US Intellectual Property Office (USPTO) for Patent Application No. 18/035,149 entitled “MODIFIED URICASE AND USES THEREOF” protecting the PEGylated uricase.

Focus on Rare Renal Indications (Preclinical Programs)

- The Company is deepening its focus on rare renal diseases by advancing PRX-119, its long-acting DNase I program.
- The Company is also collaborating with Secarna to discover RNA-based therapeutic candidates that may complement its ProCellEx platform.

Financial Outlook: Building Durable Growth and Long–Term Value

Protalix enters 2026 with a profitable commercial business through its partnerships and a focused pipeline aligned to areas of high unmet need. The Company has a strong balance sheet, with no outstanding debt or warrants. The Company believes that its current business model limits downside risk while preserving significant upside potential as the Company progresses its clinical programs, expands its commercial footprint, and pursues strategic partnerships to accelerate impact and scale.

Priorities remain consistent:

1. Support our commercial partnerships
2. Advance PRX–115 as a potential best–in–class therapy for uncontrolled gout
3. Advance rare renal programs leveraging the Company’s R&D strengths

Based on current estimates, management expects:

- Total revenue in 2026 to range from approximately $78.0 million to $83.0 million including the $25.0 million milestone which the Company is entitled to from Chiesi.
    - Full-year 2026 revenues from sales of Elfabrio without milestones to range from approximately $33.0 million to $35.0 million.

- Full-year 2026 revenues from sales of Elelyso to range from approximately $20.0 million to $23.0 million.

This outlook is not a guarantee of future performance, and stockholders should not rely on such forward-looking statements. These estimates are based on management's current estimates, which are subject to change and may be updated accordingly. See "Forward-Looking Statements" for additional information.

Fiscal Year 2025 Financial Highlights

- **Revenues from selling goods** were $51.8 million for the year ended December 31, 2025, a decrease of $1.2 million (2%) versus $53.0 million in 2024, driven primarily by a $6.8 million decline in sales to Chiesi to $22.5 million, partially offset by an increase in sales to Pfizer Inc., or Pfizer (up $5.6 million to $18.2 million), and to Fundação Oswaldo Cruz, or Fiocruz (Brazil) (up $0.03 million to $11.1 million).

  The decrease in revenues recorded from sales to Chiesi in 2025 resulted primarily from a change in the average net selling price of drug product in the applicable territory as well as changes in the quantities the Company sold to Chiesi's inventory. The increase in revenues recorded from sales to Pfizer resulted primarily from increased purchases of Elelyso by Pfizer to address unexpected manufacturing issues on their end.

- **Revenues from license and R&D services** were $0.9 million in 2025, up $0.5 million (125%) from $0.4 million in 2024. Revenues from license and R&D services are comprised primarily of revenues recognized in connection with the Company's agreements with Chiesi. Other than potential regulatory milestone payments that may become payable, the Company expects to generate minimal revenues from license and R&D services.

- **Cost of goods sold** were $27.0 million in 2025, an increase of $2.7 million (11%) versus $24.3 million in 2024. The increase in cost of goods sold was primarily the result of increase in sales to Pfizer and Fiocruz (Brazil) partially offset by a decrease in sales to Chiesi.

- **Research & development (R&D) expenses** totaled $19.6 million in 2025 (vs. $13.0 million in 2024) up $6.6 million (51%). The increase in research and development expenses resulted primarily from preparations for the RELEASE Phase 2 study of PRX-115. The Company expects to continue to incur significant and increasing research and development expenses as it progresses with the RELEASE study and commences more advanced stages of preclinical and clinical trials for certain of its other product candidates.

- **Selling, general and administrative (SG&A) expenses** were $11.7 million in 2025, a decrease of $0.5 million (4%) from $12.2 million in 2024. The decrease resulted primarily from a decrease in share-based compensation.

- **Financial income (expenses)**, **net** was an expense of $0.1 million in 2025 versus income of $0.2 million in 2024, resulting primarily from approximately $1.3 million in exchange rate expense effects, partially offset by approximately $1.0 million in reduced interest expense following the full repayment of the then outstanding senior secured convertible promissory notes, including all outstanding principal and interest, in September 2024.

- **Taxes on income** were $1.0 million in 2025, a decrease of $0.2 million (18%) compared to $1.2 million in 2024, the tax expenses resulted primarily from taxes on income mainly derived from global intangible low-taxed income (GILTI) resulting primarily from limitations

under U.S. Internal Revenue Code Section 174 (the U.S. Tax Cuts and Jobs Act).

- **Cash, cash equivalents, and short-term bank deposits** were $30.3 million on December 31, 2025.
- **Net loss** for the year ended December 31, 2025, was approximately $6.6 million, or $(0.08) per share, basic and diluted, compared to net income of $2.9 million or $0.04 per share, basic and diluted, for the same period in 2024.

Conference Call and Webcast Information
The Company will host a conference call today, March 18, 2026, at 8:00 am EDT, to review the financial results and provide a business update. To participate in the conference call, please dial the following numbers prior to the start of the call:

Conference Call Details:
Date: March 18, 2026
Time: 8:00 a.m. Eastern Daylight Time (EDT)
Toll Free: 1-877-423-9813
International: 1-201-689-8573
Israeli Toll Free: 1-809-406-247
Conference ID: 13758983
Call me™: http://bit.ly/4aOQNnE

The Call me™ feature allows you to avoid the wait for an operator; you enter your phone number on the platform and the system calls you right away.

Webcast Details:
The conference will be webcast live from the Protalix website and will be available via the following links:

Company Link: https://ir.protalix.com/news-events/events
Webcast Link: https://tinyurl.com/4jxzchdh
Conference ID: 13758983

Participants are requested to access the websites at least 15 minutes ahead of the conference to register, download and install any necessary audio software.

A replay of the call will be available for two weeks on the Events Calendar of the Investors section of the Protalix website, at the above link.

About Protalix BioTherapeutics, Inc.
Protalix is a biopharmaceutical company focused on the discovery, development, production, and commercialization of innovative therapeutics for rare diseases. Protalix has researched, developed, and currently manufactures two enzyme replacement therapies that are currently available in multiple markets. These therapies are recombinant therapeutic proteins expressed through Protalix's proprietary plant cell-based expression system, ProCellEx®. ProCellEx is a unique plant cell-based system that enables Protalix to produce recombinant proteins in an industrial-scale manner with no exposure to mammalian cells. Protalix is the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights to taliglucerase alfa, Elelyso®, for the treatment of Gaucher disease, excluding in Brazil where Protalix retains full rights.

Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of Elfabrio® which was approved by both the FDA and the European Medicines

Agency (EMA) in May 2023. Protalix's development pipeline includes, among others, two proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets: PRX–115, a plant cell-expressed recombinant PEGylated uricase for the treatment of uncontrolled gout; and PRX–119, a plant cell-expressed long-acting DNase I for the treatment of NETs-related diseases. To learn more, please visit **www.protalix.com**.

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements generally relate to future events or the Company's future financial or operating performance, including the 2026 financial outlook described above. Actual outcomes and results may differ materially from what is expressed or forecast in such forward-looking statements. The terms "anticipate," "believe," "estimate," "expect," "can," "continue," "could," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk and the final results of a clinical trial may be different than the preliminary findings of the clinical trial. Factors that might cause material differences include, among others: risks related to the commercialization of Elfabrio® (pegunigalsidase alfa-iwxj), our approved product for the treatment of adult patients with Fabry disease; risks relating to Elfabrio's market acceptance, competition, reimbursement, and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product; 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 our 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 other health regulatory authorities for our other product candidates and other risks relating to the review process; risks associated with global conditions and developments such as new or increased tariffs, new 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, operations and ability to raise additional financing if and as required and on terms acceptable to us; risks related to any transactions we may effect in the public or private equity or debt markets to raise capital to finance future research and development activities, general and administrative expenses and working capital; risks relating to our evaluation and pursuit of strategic partnerships; risks relating to our ability to manage our relationship with our collaborators, distributors, and partners, including, but not limited to, Pfizer Inc. and Chiesi

Farmaceutici S.p.A.; risks related to the amount and sufficiency of our cash and cash equivalents and short-term bank deposits; risks relating to changes to interim, top-line or preliminary data from clinical trials that we announce or publish; risks relating to the compliance by Fundação Oswaldo Cruz, or Fiocruz, an arm of the Brazilian Ministry of Health with its purchase obligations under our supply and technology transfer agreement that we entered into with Fiocruz in June 2013, which may have a material adverse effect on us and may result in our terminating such agreement; risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector; our dependence on performance by third-party providers of services and supplies, including without limitation, clinical trial services; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies; risks related to our supply of drug products to Pfizer; potential product liability risks, and risks of securing adequate levels of related insurance coverage; the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties; risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; and other factors described in our filings with the U.S. Securities and Exchange Commission. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law. You are cautioned not to place undue reliance on these forward-looking statements.

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

	December 31,	
	2024	2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,760	$ 14,680
Short-term bank deposits	15,070	15,593
Restricted deposit	-	702
Accounts receivable	2,909	8,840
Other assets	1,096	1,129
Inventories	21,243	25,729
Total current assets	$ 60,078	$ 66,673
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 462	$ 578
Property and equipment, net	4,591	4,879
Deferred income tax asset	2,856	2,516
Operating lease right of use assets	5,430	7,700
Total assets	$ 73,417	$ 82,346
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,533	$ 5,259
Other	19,588	19,875
Operating lease liabilities	1,500	1,384
Total current liabilities	$ 25,621	$ 26,518
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 559	$ 661
Operating lease liabilities	4,026	6,937
Total long term liabilities	$ 4,585	$ 7,598
Total liabilities	$ 30,206	$ 34,116
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Common Stock, $0.001 par value: Authorized - as of December 31, 2024 and 2025, 185,000,000 shares; issued and outstanding - as of December 31, 2024 and 2025, 75,850,275 and 80,425,981 shares, respectively	76	80
Additional paid-in capital	421,528	433,147
Accumulated deficit	(378,393)	(384,997)
Total stockholders' equity	43,211	48,230
Total liabilities and stockholders' equity	$ 73,417	$ 82,346

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

	Year Ended December 31,		
	2023	2024	2025
REVENUES FROM SELLING GOODS	$ 40,418	$ 52,981	$ 51,802
REVENUES FROM LICENSE AND R&D SERVICES	25,076	418	942
TOTAL REVENUE	65,494	53,399	52,744
COST OF GOODS SOLD	(22,982)	(24,319)	(26,993)
RESEARCH AND DEVELOPMENT EXPENSES	(17,093)	(12,970)	(19,569)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(14,959)	(12,193)	(11,682)
OPERATING INCOME (LOSS)	10,460	3,917	(5,500)
FINANCIAL EXPENSES	(3,180)	(1,062)	(1,191)
FINANCIAL INCOME	1,286	1,299	1,083
FINANCIAL INCOME (EXPENSES), NET	(1,894)	237	(108)
INCOME (LOSS) BEFORE TAXES ON INCOME	8,566	4,154	(5,608)
TAXES ON INCOME	(254)	(1,222)	(996)
NET INCOME (LOSS)	$ 8,312	$ 2,932	$ (6,604)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:			
BASIC	$ 0.12	$ 0.04	$ (0.08)
DILUTED	$ 0.09	$ 0.04	$ (0.08)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:			
BASIC	67,512,527	72,530,698	78,546,234
DILUTED	82,424,016	81,057,176	78,546,234