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): May 13, 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 May 13, 2026, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended March 31, 2026 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 May 13, 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: May 13, 2026

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports First Quarter 2026 Financial and Business Results

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

- Elfabrio commercial execution continues following European Commission approval of the 2 mg/kg every-4-weeks (E4W) dosing regimen; $25 million milestone received from Chiesi
- PRX-115 Phase 2 study continues to advance as planned with top-line results anticipated in the second half of 2027
- The Company reaffirms its previously stated 2026 revenue guidance of $78.0-$83.0 million including the $25.0 million milestone received from Chiesi
- Cash, cash equivalents, and short-term bank deposits were $51 million as of March 31, 2026, providing sufficient capital to fund ongoing operations including the Phase 2 RELEASE clinical trial of PRX-115

CARMIEL, Israel, May 13, 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 first quarter ended March 31, 2026, and provided a business and clinical update.

During the first quarter, the Company continued to execute against its commercial partnerships, advance its clinical and preclinical development programs, and reaffirm its strategic priorities and financial outlook for 2026.

“Protalix entered 2026 with positive momentum,” said Dror Bashan, President and Chief Executive Officer of Protalix BioTherapeutics. “With the recent regulatory progress for Elfabrio in Europe, which triggered the $25 million milestone payment, the continued enrollment of our PRX-115 Phase 2 RELEASE study, and a growing focus on rare renal diseases, we believe the company is entering a pivotal period of growth and clinical advancement. We are confident in our strategy and reaffirm our guidance for 2026. We believe our business model positions us well to generate long-term value while advancing therapies that meaningfully address unmet needs.”

First Quarter 2026 Operational Update

Elfabrio® for Fabry Disease

- Protalix and its partner, Chiesi Farmaceutici, continue to support the launch and expansion of Elfabrio across approved markets.
- Following the previously announced European Commission approval of the 2 mg/kg every-4-weeks (E4W) dosing regimen, Protalix believes Elfabrio is well-positioned to reduce treatment burden for patients with Fabry disease in the European Union without compromising efficacy.
- The E4W option enhances Elfabrio’s competitive positioning in the European Union and supports broader adoption by providing increased dosing flexibility.
- The FDA-approved dosing regimen for Elfabrio in the United States remains 1 mg/kg every 2 weeks.
- With the global Fabry market projected to reach approximately $3 billion by 2031, Elfabrio® is positioned as a leading therapy with the potential to achieve a meaningful 15% to 20% global market share, supported by strong execution through Protalix’s partnership with Chiesi.

PRX-115 for Uncontrolled Gout – RELEASE Phase 2 continues enrollment

- The RELEASE Phase 2 clinical trial (NCT07280156) of PRX-115, a recombinant PEGylated uricase, for the treatment of uncontrolled gout continues to enroll patients.
- The Company continues to anticipate top-line results in the second half of 2027.
- PRX-115 is designed as a potential best-in-class, long-acting uricase therapy, which is supported by favorable Phase 1 data, 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 of the uncontrolled gout segment, where even modest penetration represents significant commercial opportunity.

Focus on Rare Renal Indications (Preclinical Programs)

- The Company continues to advance PRX-119, its long-acting DNase I program, as part of a broader strategic focus on rare renal indications.

- The Company also continues to collaborate with Secarna to identify RNA-based therapeutic candidates that may complement its proprietary ProCellEx® platform.

Financial Outlook: Building Durable Growth and Long–Term Value

The Company operates a profitable growing 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 and preclinical 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 patients with uncontrolled gout
3. Advance rare renal programs leveraging the Company's R&D strengths

The Company reaffirms its previously stated 2026 revenue expectations:

- Total revenue in 2026 to range from approximately $78.0 million to $83.0 million including the $25.0 million milestone which the Company has received 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.

First Quarter 2026 Financial Highlights

- **Revenues from selling goods** were $7.4 million for the three months ended March 31, 2026, compared to $10.0 million for the same period in 2025. The change was primarily due to a timing shift in Pfizer's purchases this past quarter, following elevated Elelyso orders in the same period during 2025 to address unexpected manufacturing issues on their end. This timing-related impact was partially offset by $3.5 million in sales to Chiesi, which did not occur in the prior-year period.

- **Revenues from license and R&D services** were $26.3 million for the first quarter of 2026, compared to $0.1 million for the first quarter of 2025. The increase resulted primarily from a $25.0 million milestone payment received from Chiesi in connection with the approval of the E4W dosage in the European Union. The Company expects to generate minimal revenues from license and R&D services, having completed the clinical development of Elfabrio, other than potential regulatory milestone payments.

- **Cost of revenues** were $4.1 million for the first quarter of 2026, a decrease of $4.1 million (50%) compared to $8.2 million for the same period in 2025. The decrease was primarily attributable to lower sales volumes to Pfizer and Fiocruz, partially offset by increased sales to Chiesi.

- **Research & development (R&D)** expenses totaled $5.4 million for the first quarter of 2026, compared to $3.5 million for the first quarter of 2025, representing an increase of $1.9 million (56%). The increase was driven primarily by preparations for and initiation of the Phase 2 RELEASE clinical trial of PRX-115. The Company expects to continue to incur R&D expenses as the RELEASE study progresses, and additional preclinical and clinical programs advance.

- **Selling, general, and administrative (SG&A) expenses** were $3.1 million for the first quarter of 2026, an increase of $0.5 million (17%) compared to $2.6 million for the prior-year period. The increase was driven primarily by higher salary and related expenses.

- **Financial income (expenses)**, **net** was approximately $(0.0) million for the first quarter of 2026, compared to income of $0.4 million for the first quarter of 2025. The change resulted primarily from a $0.3 million exchange rate influence and $0.1 million lower interest income.

- **Taxes on income** were approximately $2.8 million for the first quarter of 2026 and tax benefit was approximately $(0.1) million for the first quarter of 2025. Income tax expense primarily reflects taxes on income derived from global intangible low-taxed income (GILTI), including the impact of capitalization requirements under Internal Revenue Code Section 174.

- **Cash, cash equivalents, and short-term bank deposits** were $51.1 million on March 31, 2026.

- **Net income** for the three months ended March 31, 2026 was $18.3 million, or $0.23 per share - basic and $0.22 per share – diluted, compared to a net loss of $3.6 million, or $(0.05) per share - basic and diluted, for the same period in 2025. The net income was driven primarily by the milestone revenue recognized from Chiesi.

Conference Call and Webcast Information
The Company will host a conference call today, May 13, 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: May 13, 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: 13760475
Call me™: https://tinyurl.com/yjww2vxn

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/ykmy9jmr
Conference ID: 13760475

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.

Investor Contact
Mike Moyer, Managing Director
LifeSci Advisors
+1-617-308-4306
mmoyer@lifesciadvisors.com

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

	March 31, 2026	December 31, 2025
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,001	$ 14,680
Short-term bank deposits	10,082	15,593
Restricted deposit	711	702
Accounts receivable	2,939	8,840
Other assets	1,149	1,129
Inventories	30,474	25,729
Total current assets	$ 86,356	$ 66,673
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 589	$ 578
Property and equipment, net	5,153	4,879
Deferred income tax asset	2,445	2,516
Operating lease right of use assets	7,793	7,700
Total assets	$ 102,336	$ 82,346
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,285	$ 5,259
Other	21,670	19,875
Operating lease liabilities	1,433	1,384
Total current liabilities	$ 27,388	$ 26,518
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 671	$ 661
Operating lease liabilities	7,048	6,937
Total long-term liabilities	$ 7,719	$ 7,598
Total liabilities	$ 35,107	$ 34,116
COMMITMENTS		
STOCKHOLDERS' EQUITY	67,229	48,230
Total liabilities and stockholders' equity	$ 102,336	$ 82,346

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

	Three Months Ended	
	March 31, 2026	March 31, 2025
REVENUES FROM SELLING GOODS	$ 7,419	$ 9,995
REVENUES FROM LICENSE AND R&D SERVICES	26,331	118
TOTAL REVENUE	33,750	10,113
COST OF REVENUES	(4,127)	(8,180)
RESEARCH AND DEVELOPMENT EXPENSES	(5,426)	(3,475)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(3,051)	(2,603)
OPERATING INCOME (LOSS)	21,146	(4,145)
FINANCIAL EXPENSES	(193)	(6)
FINANCIAL INCOME	188	419
FINANCIAL INCOME (EXPENSES), NET	(5)	413
INCOME (LOSS) BEFORE TAXES ON INCOME	21,141	(3,732)
TAXES ON INCOME (TAX BENEFIT)	2,824	(113)
NET INCOME (LOSS)	$ 18,317	$ (3,619)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:		
BASIC	$ 0.23	$ (0.05)
DILUTED	$ 0.22	$ (0.05)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:		
BASIC	79,848,892	76,611,980
DILUTED	83,048,596	76,611,980