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): November 10, 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 November 10, 2026, Protalix BioTherapeutics, Inc. issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 November 10, 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: November 10, 2026

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports Third Quarter 2026 Financial and Business Results

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

- Total revenues increased by $32.0 million year to date to $75.6 million, from $43.6 million for the same period in 2025
- Net income was $4.0 million for the third quarter, up from $2.4 million in the third quarter of 2025, and net income was $26.1 million for the nine months ended September 30, 2026
- Management expects to meet or exceed 2026 guidance for total revenues of approximately $78.0 million to $83.0 million
- The PRX-115 Phase 2 RELEASE study remains on track, aiming to improve adherence and durability of response in uncontrolled gout, a substantial unmet need; top-line results anticipated in the second half of 2027
- Cash, cash equivalents, and short-term bank deposits were $48.5 million as of September 30, 2026

CARMIEL, Israel, November 10, 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 third quarter ended September 30, 2026, and provided a business and clinical update.

"We concluded the first nine months of 2026 with revenues of $75.6 million, reflecting our continued progress and growing financial strength which supports our ability to execute our strategy and advance our key priorities," said Dror Bashan, President and Chief Executive Officer of Protalix BioTherapeutics. "We end the quarter with cash and deposits of $48.5 million, a position of strength that enables us to continue advancing PRX-115 for uncontrolled gout. Uncontrolled gout is a disease with low quality of life and high unmet need and represents a blockbuster uricase market opportunity. Current uricase therapy has challenges including infusion burden, immunogenicity with loss of efficacy, and safety concerns. We designed PRX-115 for reduced immunogenicity and less frequent dosing that could reduce infusion burden and improve patient adherence. We look forward to top-line results from the RELEASE study in the second half of 2027."

Third Quarter 2026 Operational Update

Elfabrio® for Fabry Disease

- Elfabrio received marketing authorization in Brazil for both the every-two-weeks and the every-four-weeks dosing regimens. Chiesi Global Rare Diseases is the Company's partner for the global development and commercialization of Elfabrio.

PRX-115 for uncontrolled gout

Phase 2 RELEASE Study

- Patient enrollment continues in the Company's Phase 2 RELEASE study (NCT07280156) of PRX-115, a recombinant PEGylated uricase, for the treatment of uncontrolled gout; anticipated top-line results in the second half of 2027.

ACR 2026 Phase 1 Data

- The Company is presenting a poster at the American College of Rheumatology (ACR) Convergence 2026, which will be made available on the publications page of the Company's website.
- The analysis being presented at ACR Convergence 2026 covers the 18 mg, 24 mg and 36 mg cohorts; there were six participants per cohort who received a single infusion and were followed for 85 days.
- The Company previously reported that higher single doses of PRX 115 lowered mean plasma uric acid for longer durations in participants with elevated plasma uric acid levels (ACR 2024).
- New individual patient data presented at ACR 2026 reinforce this finding and show the effect associated with PRX-115 plasma levels remaining measurable for up to 85 days.
- These data support the potential of PRX-115 to be a best-in-class uricase therapy with less frequent dosing.

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, as well as other research collaborations.

Financial Outlook: Building Durable Growth and Long–Term Value

The Company has no outstanding debt or warrants.

Priorities remain consistent:

1. Support our commercial partners through the manufacture and supply of our products
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 2026 revenue guidance and expects to meet or exceed these ranges:

- Total revenues of approximately $78.0 million to $83.0 million, including the $25.0 million milestone payment received from Chiesi in Q1 2026.
    - Full-year 2026 revenues from sales of Elfabrio, excluding milestones, of approximately $33.0 million to $35.0 million.
    - Full-year 2026 revenues from sales of Elelyso® of 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.

Third Quarter and Year-to-Date 2026 Financial Highlights

- **Revenues from selling goods** were $21.8 and $49.1 million for the three and nine months ended September 30, 2026, respectively, compared to $17.7 and $43.1 million for the same periods in 2025, an increase of $4.1 and $6.0 million, respectively. The increase was driven primarily by higher sales to Chiesi. The increase for the nine months ended September 30, 2026 compared to nine months ended September 30, 2025 was driven primarily by higher sales to Chiesi, partially offset by lower purchases by Pfizer Inc. mainly due to Pfizer's manufacturing issues in the previous year and lower sales to Fiocruz (Brazil). Changes in sales to Pfizer and Fiocruz (Brazil) in the third quarter of 2026 resulted primarily from the timing of deliveries.

- **Revenues from license and R&D services** were $0.1 and $26.5 million for the three and nine months ended September 30, 2026, respectively, compared to $0.2 and $0.5 million for the same periods in 2025. The decrease in the third quarter was due to a lower amount of services provided to Chiesi. The increase in the nine months resulted from the $25.0 million milestone payment received from Chiesi in connection with the E4W dosage approval in the EU in the first quarter of 2026.

- **Cost of revenues** were $7.9 and $19.8 million for the three and nine months ended September 30, 2026, respectively, compared to $8.3 and $22.4 million for the same periods in 2025. The decrease in the third quarter resulted primarily from lower sales to Fiocruz (Brazil), partially offset by higher sales to Chiesi and Pfizer. The decrease in the nine months resulted primarily from lower sales to Pfizer and Fiocruz (Brazil), partially offset by higher sales to Chiesi.

- **Research and development (R&D) expenses** were $6.9 and $16.7 million for the three and nine months ended September 30, 2026, respectively, an increase of $2.4 and $2.8 million compared to $4.5 and $13.9 million for the same periods in 2025. The increase resulted primarily from higher subcontractor-related expenses, mainly related to the RELEASE study, and for the nine months, higher salary and related expenses, partially offset by a grant of $1.0 and $3.1 million, respectively, recorded under the new R&D law as a reduction of R&D expenses. 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 and $9.2 million for the three and nine months ended September 30, 2026, respectively, an increase of $0.2 and $1.0 million, respectively, compared to $2.9 and $8.2 million for the prior-year periods. The increase was driven primarily by $0.7 million in higher salary and related expenses, $0.2 million in selling expenses and $0.1 million in other expenses for the nine months and by $0.1 million in higher professional fees and $0.1 million in higher salary and related expenses for the three months.

- **Financial income, net** was $0.6 and $0.8 million for the three and nine months ended September 30, 2026, respectively, compared to $0.1 million and less than $0.1 million for the same periods in 2025. The increase resulted primarily from exchange rate fluctuations between the U.S. dollar and the New Israeli Shekel and higher interest income.

- **Taxes on income** were $0.7 and $4.6 million for the three and nine months ended September 30, 2026, respectively, compared to a tax benefit of $0.1 million and tax expense of $0.3 million for the same periods in 2025. The tax expense resulted primarily from taxes on income derived from global intangible low-taxed income (GILTI) resulting from limitations under IRC Section 174 and from taxes related to the Company's receipt of the $25 million milestone payment in the first quarter of 2026.

- **Cash, cash equivalents, and short-term bank deposits** were $48.5 million at September 30, 2026.

- **Net income** for the three months ended September 30, 2026 was $4.0 million, or $0.05 per share, basic and diluted, compared to $2.4 million, or $0.03 per share, basic and diluted, for the same period in 2025. Net income for the nine months ended September 30, 2026 was $26.1million, or $0.33 per share, basic, and $0.31 per share, diluted, compared to a net loss of $1.1 million, or $0.01 per share, basic and diluted, for the same period in 2025.

Conference Call and Webcast Information
The Company will host a conference call today, November 10, at 8:00 am ET, 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: November 10, 2026
Time: 8:00 a.m. Eastern Time (ET)
Toll Free: 1-877-423-9813
International: 1-201-689-8573
Israeli Toll Free: 1-809-406-247
Conference ID: 13763420
Call me™: https://tinyurl.com/3awxvdvm
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/ye6k6b3n
Conference ID: 13763420

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 Uncontrolled Gout
Gout is a metabolic disorder characterized by elevated blood uric acid that causes recurrent inflammatory arthritis and joint damage. An estimated 11.3 million people in the U.S. have gout.[1] Rheumatologists report that approximately 25% of their patients have blood uric acid levels above target, which can lead to uncontrolled gout.[2] An estimated 180,000 patients in the U.S. have uncontrolled gout.[2] Uncontrolled gout is a severe disease with high morbidity, severe pain, and low quality of life.

About PRX-115
PRX-115 is a recombinant PEGylated uricase in development for uncontrolled gout, produced using Protalix's ProCellEx® plant cell-based protein expression platform. Current uricase therapy has challenges including infusion burden, immunogenicity with loss of efficacy, and safety concerns. PRX-115 is designed for high specific activity, prolonged circulating half-life, and reduced immunogenicity.[3] In the Phase 1 study of adults with elevated plasma uric acid levels, single infusions of PRX-115 lowered plasma uric acid levels rapidly and were generally well tolerated. At 36 mg, mean plasma uric acid stayed below the 6.0 mg/dL target for up to 12 weeks after a single infusion. Protalix believes PRX-115 has best-in-class potential for uncontrolled gout.

About the Phase 2 RELEASE Study (PRX-115)
RELEASE (NCT07280156) is a Phase 2, double-blind, placebo-controlled study of PRX-115 in patients with uncontrolled gout. The study tests a fixed 36 mg dose in five treatment arms of 30 patients each: PRX-115 every 4 weeks without methotrexate, PRX-115 every 4, 6, or 8 weeks with methotrexate, and placebo. The primary endpoint is the proportion of patients who demonstrated a reduction in serum uric acid levels to below 6.0 mg/dL for at least 80% of the time during Month 6. Top-line results are expected in the second half of 2027.

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.

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[1] GlobalData, August 2025
[2] Protalix internal research and proprietary market research (75 rheumatologists).
[3] Schwabe C, Cohen-Barak O, Cole A, et al. Prolonged plasma urate-lowering after a single intravenous administration of PRX-115, a novel PEGylated uricase, in participants with elevated urate levels. Presented at: ACR Convergence 2024. Abstract L05.

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 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 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 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. 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)

	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

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