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 13, 2025

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 13, 2025, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 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 November 13, 2025
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 13, 2025

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports Third Quarter 2025 Financial and Business Results

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

CARMIEL, Israel, November 13, 2025 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: PLX), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx® plant cell-based protein expression system, today reported financial results for the quarter ended September 30, 2025, and provided a financial and business update.

"We are pleased to report total revenues of $43.6 million for the first nine months of 2025, an increase of 24%, compared to the same period in 2024. Our total revenues for the third quarter were $17.9 million which reflects a decrease of 1%, compared to revenues for the same period of 2024," said Dror Bashan, Protalix's President and Chief Executive Officer. "We recognize revenues from sales of our products to Chiesi, Pfizer, and Fiocruz in Brazil, and their purchases vary from quarter to quarter as they control their own inventories. Overall, these revenues reflect the continued commercial success of our enzyme replacement therapies and provide a strong foundation to support our research and development efforts."

"We are particularly excited about PRX-115, our recombinant PEGylated uricase candidate under development for the treatment of uncontrolled gout, which we believe has the potential to be a differentiating treatment for uncontrolled gout," continued Mr. Bashan. "Based on encouraging first-in-human data from our phase 1 clinical trial of PRX-115, we believe it has the potential to be a best-in-class therapy with a long-acting profile that could improve patient compliance and outcomes. We are planning to initiate a phase 2 clinical trial of PRX-115 later this year."

Corporate Highlights

- In October 2025, we submitted an Investigational New Drug (IND) to the US Food and Drug Administration in connection with our planned phase 2 clinical trial of PRX-115 for the potential treatment of uncontrolled gout. The IND has become effective following the FDA's standard 30-day review period.
- In November 2025, Chiesi Global Rare Diseases, a business unit of the Chiesi Group, with our collaboration requested a re-examination of the recent negative opinion issued in October 2025 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on Chiesi's request for a Variation Submission covering the 2 mg/kg body weight infused every 4 weeks (E4W) dosing regimen for Elfabrio (pegunigalsidase alfa), in addition to the currently approved 1 mg/kg body weight infused every 2 weeks (E2W) dosing regimen.
- The 1 mg/kg E2W regimen is unaffected and remains approved as a dosing regimen of Elfabrio in the EU.

Third Quarter 2025 Financial Highlights

- We recorded revenues from selling goods of $17.7 million during the three months ended September 30, 2025, a decrease of $0.1 million, or 1%, compared to revenues of $17.8 million for the three months ended September 30, 2024. These revenues consist of $8.8 million in sales of Elfabrio to Chiesi, $2.8 million in sales of Elelyso to Pfizer and $6.1 million in sales of alfataliglicerase (Elelyso) to Fiocruz (Brazil).
- We recorded revenues from license and R&D services of $0.2 million for the three months ended September 30, 2025, an increase of $0.1 million, or 100%, compared to $0.1 million for the same period in 2024. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with our license and supply agreements with Chiesi. 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 goods sold was $8.3 million for the three months ended September 30, 2025, a decrease of $0.1 million, or 1%, from $8.4 million for the same period in 2024. The decrease was primarily the result of the decrease in sales to Chiesi and Pfizer, partially offset by the increase in sales to Fiocruz (Brazil).
- For the three months ended September 30, 2025, our total research and development expenses were approximately $4.5 million comprised of approximately $2.6 million of salary and related expenses, approximately $0.5 million of subcontractor-related expenses, approximately $0.5 million of materials-related expenses and approximately $0.9 million of other expenses. For the same period in 2024, our total research and development expenses were approximately $3.0 million comprised of approximately $1.6 million of salary and related expenses, approximately $0.6 million of subcontractor--related expenses, approximately $0.2 million of materials-related expenses and approximately $0.6 million of other expenses. The increase of $1.5 million, or 50%, compared to the same period of 2024 resulted primarily from preparations for the planned phase 2 clinical trial of PRX-115.
- We expect to continue to incur significant research and development expenses as we enter into a more advanced stage of preclinical and clinical trials, including the initiation of the phase 2 clinical trial of PRX-115 and as we develop additional research stage programs.
- Selling, general and administrative expenses were $2.9 million for the three months ended September 30, 2025, an increase of $0.3 million, or 12%, compared to $2.6 million for the same period in 2024. The increase resulted primarily from an increase of $0.1 million in salary and related expenses and an increase of $0.2 million in selling expenses.
- Financial income, net was $0.1 million for the three months ended September 30, 2025, compared to financial expenses, net of $0.1 million for the same period in 2024. The difference resulted primarily from lower notes interest expenses due to the September 2024 repayment in full of all the outstanding principal and interest payable under our then outstanding convertible promissory notes, or the 2024 Notes.
- We recorded a tax benefit of approximately $0.1 million for the three months ended September 30, 2025, compared to tax expenses of approximately $0.6 million for the same period in 2024. The tax benefit resulted primarily from taxes on income mainly derived from GILTI income in respect of Section 174 of the U.S. Tax Cuts and Jobs Act

of 2017, or the TCJA. On July 4, 2025, tax reform legislation was enacted in the United States through the passage of H.R.1, One Big Beautiful Bill Act, or HR1, 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.

- Net income for the three months ended September 30, 2025 was approximately $2.4 million, or $0.03 per share, basic and diluted, compared to net income of $3.2 million, or $0.04 per share, basic and $0.03 per share, diluted, for the same period in 2024.

Year-to-Date 2025 Financial Highlights

- We recorded revenues from selling goods of $43.1 million for the nine months ended September 30, 2025, an increase of $8.3 million, or 24%, compared to revenues of $34.8 million for the same period in 2024. These revenues consist of $18.6 million in sales of Elfabrio to Chiesi, $15.4 million in sales of Elelyso to Pfizer and $9.1 million in sales of alfataliglicerase (Elelyso) to Fiocruz (Brazil).
- We recorded revenues from license and R&D services of $0.5 million for the nine months ended September 30, 2025, an increase of $0.1 million, compared to $0.4 million for the same period in 2024. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with our license and supply agreements with Chiesi. 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 goods sold was $22.4 million for the nine months ended September 30, 2025, an increase of $2.0 million, or 10%, from $20.4 million for the same period in 2024. The increase was primarily the result of increased sales to Chiesi and Pfizer, partially offset by a decrease in sales to Fiocruz (Brazil).
- For the nine months ended September 30, 2025, our total research and development expenses were approximately $13.9 million, comprised of approximately $6.5 million of salary and related expenses, $4.3 million of subcontractor-related expenses, $0.9 million of materials-related expenses, and $2.2 million of other expenses. For the same period in 2024, R&D expenses were approximately $8.8 million comprised of approximately $4.8 million of salary and related expenses, approximately $1.6 million of subcontractor-related expenses, approximately $0.5 million of materials-related expenses and approximately $1.9 million of other expenses. The $5.1 million, or 58%, increase compared to the same period of 2024 resulted primarily from preparations for the planned phase 2 clinical trial of PRX-115.
- Selling, general and administrative expenses were $8.2 million for the nine months ended September 30, 2025, a decrease of $1.0 million, or 11%, compared to $9.2 million for the same period in 2024. The decrease resulted primarily from lower salary and selling expenses.
- Financial income, net was $0.01 million for the nine months ended September 30, 2025, compared to financial income, net of $0.1 million for the same period in 2024. The decrease resulted primarily from exchange rate costs and lower interest income on bank deposits, partially offset by lower notes interest expenses due to the September

2024 repayment in full of all the outstanding principal and interest payable under the 2024 Notes.

- We recorded tax expenses of approximately $0.3 million for the nine months ended September 30, 2025, compared to tax expenses of approximately $0.4 million for the same period in 2024. The tax expenses resulted primarily from taxes on income mainly derived from GILTI income in respect of the TCJA. HR1 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.
- Net loss for the nine months ended September 30, 2025 was approximately $1.1 million, or $(0.01) per share, basic and diluted, compared to a net loss of $3.6 million, or $(0.05) per share, for the same period in 2024.

At September 30, 2025, we had $29.4 million in cash and cash equivalents and short-term bank deposits, which we believe are sufficient to satisfy our capital needs for at least 12 months from the date we issue our quarterly report for the quarter ended September 30, 2025.

Conference Call and Webcast Information
We will host a conference call today, November 13, 2025, at 8:00 am EST, 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:	Thursday, November 13, 2025
Time:	8:00 a.m. Eastern Standard Time (EST)
Toll Free:	1-877-423-9813
International:	1-201-689-8573
Israeli Toll Free:	1-809-406-247
Conference ID:	13757080
Call me™:	http://bit.ly/4qJnnhY

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://bit.ly/4nJBRM1
Conference ID:	13757080

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 development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx. It 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. This unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights to taliglucerase alfa for the treatment of Gaucher disease, Protalix's first product manufactured through ProCellEx, excluding in Brazil, where Protalix retains full rights. Protalix's second product, Elfabrio®, was approved by both the FDA and the European Medicines Agency in May 2023.

Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of Elfabrio. Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: PRX–115, a plant cell-expressed recombinant PEGylated uricase for the treatment of uncontrolled gout; PRX–119, a plant cell-expressed long acting DNase I for the treatment of NETs-related diseases; and others.

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. 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 for 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; the possible disruption of our operations due to military actions conducted by Israel with the Hamas terrorist organization located in the Gaza Strip, the Hezbollah in Lebanon, the Houthis which control parts of Yemen, Iran 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 a greater regional conflict; risks related to the regulatory approval and commercial success of our other product and product candidates, if approved; risks related to our expectations with respect to the projected market of our products and product candidates; failure or delay in the commencement or completion of our preclinical studies and clinical trials, which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of

medical investigators and institutional review boards to follow our clinical protocols; inability to monitor patients adequately during or after treatment; and/or lack of sufficient funding to finance our clinical trials; delays in the approval or potential rejection of any applications we file with the FDA, EMA or other health regulatory authorities for our other product candidates, including the requested a re-examination of the negative opinion issued by the CHMP regarding the proposed dosing regimen of 2 mg/kg body weight infused E4W for Elfabrio, and other risks relating to the review process; risks associated with global conditions and developments such as new or increased tariffs, new trade restrictions, supply chain challenges, the inflationary environment and tight labor market, and instability in the banking industry, which may adversely impact our business, operations and ability to raise additional financing if and as required and on terms acceptable to us; risks related to any transactions we may effect in the public or private equity or debt markets to raise capital to finance future research and development activities, general and administrative expenses and working capital; risks relating to our evaluation and pursuit of strategic partnerships; the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy and that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks relating to our ability to manage our relationship with our collaborators, distributors or partners, including, but not limited to, Pfizer and Chiesi; risks related to the amount and sufficiency of our cash and cash equivalents and short-term bank deposits; risks relating to changes to interim, top-line or preliminary data from clinical trials that we announce or publish; risks relating to the compliance by Fundação Oswaldo Cruz, an arm of the Brazilian Ministry of Health, with its purchase obligations under our supply and technology transfer agreement, which may have a material adverse effect on us and may also result in the termination of such agreement; risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector; our dependence on performance by third-party providers of services and supplies, including without limitation, clinical trial services; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies; risks related to our supply of drug products to Pfizer; potential product liability risks, and risks of securing adequate levels of related insurance coverage; the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties; 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.

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

	September 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 13,647	$ 19,760
Short-term bank deposits	15,723	15,070
Accounts receivable	14,425	2,909
Other assets	1,452	1,096
Inventories	21,255	21,243
Total current assets	$ 66,502	$ 60,078
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 549	$ 462
Property and equipment, net	4,724	4,591
Deferred income tax asset	2,679	2,856
Operating lease right of use assets	7,810	5,430
Total assets	$ 82,264	$ 73,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,375	$ 4,533
Other	15,173	19,588
Operating lease liabilities	1,397	1,500
Total current liabilities	$ 21,945	$ 25,621
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 631	$ 559
Operating lease liabilities	6,780	4,026
Total long term liabilities	$ 7,411	$ 4,585
Total liabilities	$ 29,356	$ 30,206
COMMITMENTS		
STOCKHOLDERS' EQUITY	52,908	43,211
Total liabilities and stockholders' equity	$ 82,264	$ 73,417

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, 2025	September 30, 2024	September 30, 2025	September 30, 2024
REVENUES FROM SELLING GOODS	$ 43,108	$ 34,820	$ 17,673	$ 17,839
REVENUES FROM LICENSE AND R&D SERVICES	514	361	178	120
TOTAL REVENUE	43,622	35,181	17,851	17,959
COST OF GOODS SOLD	(22,374)	(20,433)	(8,324)	(8,375)
RESEARCH AND DEVELOPMENT EXPENSES	(13,934)	(8,846)	(4,467)	(2,998)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(8,156)	(9,194)	(2,929)	(2,595)
OPERATING INCOME (LOSS)	(842)	(3,292)	2,131	3,991
FINANCIAL EXPENSES	(808)	(1,056)	(180)	(299)
FINANCIAL INCOME	818	1,186	288	151
FINANCIAL INCOME (EXPENSES), NET	10	130	108	(148)
INCOME (LOSS) BEFORE TAXES ON INCOME	(832)	(3,162)	2,239	3,843
TAXES ON INCOME (TAX BENEFIT)	268	400	(116)	607
NET INCOME (LOSS)	$ (1,100)	$ (3,562)	$ 2,355	$ 3,236
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ (0.01)	$ (0.05)	$ 0.03	$ 0.04
DILUTED	$ (0.01)	$ (0.05)	$ 0.03	$ 0.03
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	78,225,112	73,301,091	79,281,685	73,549,745
DILUTED	78,225,112	73,301,091	80,814,564	81,217,068