Protalix BioTherapeutics Reports Second Quarter 2025 Financial and Business Results

August 14, 2025

Company to host conference call and webcast today at 8:30 a.m. EDT

CARMIEL, Israel, Aug. 14, 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 June 30, 2025, and provided a business and clinical update.

"We experienced a 50% increase in revenues from selling goods in the first half of 2025 compared to the same period in 2024," said Dror Bashan, Protalix's President and Chief Executive Officer. "The increase in revenues was driven primarily by sales of Elfabrio® to Chiesi. Chiesi is an ideally suited partner for commercialization of Elfabrio for Fabry disease, which represents a global market of approximately $2.3 billion currently and which is forecasted to grow to $3.2 billion by 2030. As we are still in the early launch phase for Elfabrio, we expect global ordering patterns to fluctuate quarterly while underlying demand characteristics stabilize, the launch matures, and Elfabrio market share expands. We are confident in the growth of our Elfabrio franchise over the long term."

"We continue to advance in our development efforts for PRX-115, our recombinant PEGylated uricase product candidate in development as a potential treatment for uncontrolled gout. We anticipate initiation of a randomized Phase 2 trial in the second half of 2025 and enrollment of the first patient in the fourth quarter of 2025. We look forward to continuing to execute on our strategic plan," added Mr. Bashan.

"As we recently announced, Eyal Rubin is stepping down as our Chief Financial Officer after six years of dedicated service to Protalix. Eyal and I have worked closely and collaboratively on Protalix's transformation. He contributed greatly to strengthening the Company's capital and preparing us for growth. On behalf of our Board of Directors and the Protalix family, we thank Eyal for all of his contributions, and wish him continued and well-earned success in the future," continued Mr. Bashan. "Eyal is to be succeeded by Gilad Mamlok. Gilad is a seasoned financial executive with deep experience in healthcare and technology companies, and has an extensive background in capital markets transactions, mergers and acquisitions and business development. We are happy to welcome Gilad to the team and have every confidence that he will play an important role in Protalix's management as we continue to work toward future growth."

Second Quarter 2025 and Recent Business Highlights

Corporate Highlights

- Appointment of Gilad Mamlok to serve as the Company's new Senior Vice President and Chief Financial Officer, effective August 24, 2025, succeeding Eyal Rubin. To ensure a seamless transition, Mr. Mamlok has joined the company and is working alongside Mr. Rubin. After his tenure as Chief Financial Officer ends, Mr. Rubin will continue to be available to the Company as necessary until October 2025.
- Company has been added to the Russell 3000® and Russell 2000® Indexes, effective as of the U.S. market close on June 27, 2025, as part of the 2025 Russell indexes annual reconstitution.
- The European Medicine Agency continues its evaluation of Chiesi's variation submission for the Elfabrio label to include a dose of 2 mg/kg administered every four weeks in adult patients with Fabry disease. The variation submission was accepted for review in December 2024.

Second Quarter 2025 Financial Highlights

- We recorded revenues from selling goods of $15.4 million during the three months ended June 30, 2025, an increase of $2.1 million, or 16%, compared to revenues of $13.3 million for the three months ended June 30, 2024. The increase resulted primarily from an increase of $8.0 million in sales to Chiesi, partially offset by a decrease of $4.7 million in sales to Fiocruz (Brazil) and of $1.2 million in sales to Pfizer.

- We recorded revenues from license and R&D services of $0.2 million for the three months ended June 30, 2025, and June 30, 2024. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. We expect to generate minimal revenues from license and R&D services other than potential regulatory milestone payments.

- Cost of goods sold was $5.9 million for the three months ended June 30, 2025, a decrease of $3.6 million, or 38%, from cost of goods sold of $9.5 million for the three months ended June 30, 2024. The decrease in cost of goods sold was primarily the result of the decrease in sales to Pfizer and Fiocruz (Brazil) partially offset by the increase in sales to Chiesi.

- For the three months ended June 30, 2025, our total research and development expenses were approximately $6.0 million comprised of approximately $3.0 million in subcontractor-related expenses, approximately $2.0 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.8 million of other expenses. For the three months ended June 30, 2024, our total research and development expenses were approximately $3.0 million comprised of approximately $1.6 million of salary and related expenses, approximately $0.5 million in subcontractor-related expenses, approximately $0.2 million of materials-related expenses and approximately $0.7 million of other expenses. Total increase in research and developments expenses for the three months ended June 30, 2025 was $3.0 million, or 100%,

compared to research and developments expenses of $3.0 million for the three months ended June 30, 2024. The increase in research and development expenses resulted primarily from preparations for the planned phase II clinical trial of PRX-115. We expect to continue to incur significant, increasing research and development expenses as we enter into a more advanced stage of preclinical and clinical trials for certain of our product candidates.

- Selling, general and administrative expenses were $2.6 million for the three months ended June 30, 2025, a decrease of $0.9 million, or 26%, compared to $3.5 million for the three months ended June 30, 2024. The decrease resulted primarily from a decrease of $0.6 million in salary and related expenses and a decrease of $0.3 million in selling expenses.

- Financial expenses, net was $0.5 million for the three months ended June 30, 2025, compared to financial income, net of $0.2 million for the three months ended June 30, 2024. The increase in financial expenses, net 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 convertible promissory notes then outstanding.

- We recorded a tax expense of approximately $0.5 million for the three months ended June 30, 2025, compared to a tax benefit of approximately $(0.1) million for the three months ended June 30, 2024. The tax expenses or benefits resulted primarily from taxes on income mainly derived from GILTI income mainly in respect of Section 174 of the U.S. Tax Cuts and Jobs Act of 2017, or the TCJA. Effective in 2022, Section 174 of the TCJA requires all U.S. companies, for tax purposes, to capitalize and subsequently amortize R&D expenses that fall within the scope of Section 174 over five years for research activities conducted in the United States and over 15 years for research activities conducted outside of the United States, rather than deducting such costs in the current year. On July 4, 2025, tax reform legislation was enacted in the United States through the passage of H.R.1, the One Big Beautiful Bill Act, which includes significant corporate tax changes, including a restoration of the current deductibility for domestic research expenditures beginning in 2025, with transition options for previously capitalized amounts. We continue to evaluate the impact that the new legislation will have on the consolidated financial statements.

- At June 30, 2025, we had $33.4 million in cash and cash equivalents and short-term bank deposits.

- Net income for the three months ended June 30, 2025 was approximately $164,000, or $0.00 per share, basic and diluted, compared to net loss of $2.2 million, or $(0.03) per share, basic and diluted, for the same period in 2024.

Conference Call and Webcast Information

We will host a conference call today, August 14, 2025, at 8:30 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: Thursday, August 14, 2025
Time: 8:30 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: 13755073
Call me™: https://tinyurl.com/6uc7hkxf

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/yc272tbr
Conference ID: 13755073

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 the war declared by Israel's security cabinet against the Hamas terrorist organization located in the Gaza Strip, the military campaign against the Hezbollah and other terrorist activities and armed conflict, 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, 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.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	June 30, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,895	$ 19,760
Short-term bank deposits	15,503	15,070
Accounts receivable – Trade	9,443	2,909
Other assets	1,513	1,096
Inventories	21,131	21,243
Total current assets	$ 65,485	$ 60,078
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 520	$ 462

Property and equipment, net	4,746	4,591
Deferred income tax asset	2,738	2,856
Operating lease right of use assets	4,997	5,430
Total assets	$ 78,486	$ 73,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,689	$ 4,533
Other	15,930	19,588
Operating lease liabilities	1,472	1,500
Total current liabilities	$ 24,091	$ 25,621
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 615	$ 559
Operating lease liabilities	3,877	4,026
Total long term liabilities	$ 4,492	$ 4,585
Total liabilities	$ 28,583	$ 30,206
COMMITMENTS		
STOCKHOLDERS' EQUITY	49,903	43,211
Total liabilities and stockholders' equity	$ 78,486	$ 73,417

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

	Six Months Ended		Three Months Ended	
	June 30, 2025	June 30, 2024	June 30, 2025	June 30, 2024
REVENUES FROM SELLING GOODS	$ 25,435	$ 16,981	$ 15,440	$ 13,304
REVENUES FROM LICENSE AND R&D SERVICES	336	241	218	170
TOTAL REVENUE	25,771	17,222	15,658	13,474
COST OF GOODS SOLD	(14,050)	(12,058)	(5,870)	(9,456)
RESEARCH AND DEVELOPMENT EXPENSES	(9,467)	(5,848)	(5,992)	(2,961)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(5,227)	(6,599)	(2,624)	(3,484)
OPERATING INCOME (LOSS)	(2,973)	(7,283)	1,172	(2,427)
FINANCIAL EXPENSES	(628)	(757)	(783)	(367)
FINANCIAL INCOME	530	1,035	272	522
FINANCIAL INCOME (EXPENSES), NET	(98)	278	(511)	155
INCOME (LOSS) BEFORE TAXES ON INCOME	(3,071)	(7,005)	661	(2,272)
TAXES ON INCOME (TAX BENEFIT)	384	(207)	497	(69)
NET INCOME (LOSS)	$ (3,455)	$ (6,798)	$ 164	$ (2,203)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ (0.04)	$ (0.09)	$ 0.00	$ (0.03)
DILUTED	$ (0.04)	$ (0.09)	$ 0.00	$ (0.03)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	77,651,330	73,172,980	78,663,884	73,308,281
DILUTED	77,651,330	73,172,980	81,271,610	73,308,281

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