



Protalix BioTherapeutics Reports First Quarter 2025 Financial and Business Results

May 9, 2025

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

CARMIEL, Israel, May 9, 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 March 31, 2025, and provided a business and clinical update.

"We had another solid quarter, with an increase in revenues from selling goods compared to the prior year quarter," said Dror Bashan, Protalix's President and Chief Executive Officer. "Given the promising results obtained in 2024 from our first-in-human study of our gout candidate, PRX-115, we are focused on building on the momentum and working toward initiating a phase II clinical trial in patients with gout later this year. At the same time, we continued to evaluate additional pipeline candidates for potential further development, including PRX-119 as well as various early-stage clinical assets."

First Quarter 2025 and Recent Business and Clinical Highlights

Pipeline Developments

PRX-115

- In 2024, we successfully completed the First-in-Human (FIH) phase I clinical trial of PRX-115, our recombinant PEGylated uricase product candidate in development as a potential treatment for uncontrolled gout. The study is designed to evaluate the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD; reduction of uric acid) following a single dose of PRX-115 in subjects with elevated uric acid levels. We are in the advance stages of preparations for the phase II clinical trial we expect to commence during the second half of 2025.
 - The preliminary results of the FIH study demonstrate that PRX-115 has the potential to offer an effective uric acid-lowering treatment with an added benefit of a potentially wide dosing interval, which may enhance patient compliance and treatment flexibility. Further studies are needed to confirm the long-term safety and efficacy of PRX-115 in the gout patient population.
 - The results were presented in a late-breaking poster at the American College of Rheumatology (ACR) Convergence 2024, being held November 14-19, 2024 at the *Walter E. Washington Convention Center* in *Washington, D.C.* A copy of the poster is available on the Protalix website here: https://protalix.com/sites/default/files/PRX-115_SAD_Poster_ACR_2024_4Nov2024.pdf.

Pegunigalsidase alfa

- In March 2025, our global development and commercial partner, Chiesi Global Rare Diseases, announced multiple presentations on pegunigalsidase alfa and Fabry Disease at the 21st *Annual WORLDSymposium™* Research Meeting. The Poster presentations are available in the [publications section](#) of [Protalix's website](#).

First Quarter 2025 Financial Highlights

- We recorded revenues from selling goods of \$10.0 million during the three months ended March 31, 2025, an increase of \$6.3 million, or 170%, compared to revenues of \$3.7 million for the three months ended March 31, 2024. The increase resulted primarily from an increase of \$5.9 million in sales to Pfizer Inc. and an increase of \$0.4 million in sales to Fundação Oswaldo Cruz, or Fiocruz (Brazil).
- We recorded revenues from license and R&D services of \$0.1 million for the three months ended March 31, 2025 and the three months ended March 31, 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. We expect to generate minimal revenues from license and R&D services other than potential regulatory milestone payments.
- Cost of goods sold was \$8.2 million for the three months ended March 31, 2025, an increase of \$5.6 million, or 215%, from cost of goods sold of \$2.6 million for the three months ended March 31, 2024. The increase in cost of goods sold resulted primarily from an increase in sales to Pfizer and Fiocruz (Brazil).
- For the three months ended March 31, 2025, our total research and development expenses were approximately \$3.5 million comprised of approximately \$1.8 million of salary and related expenses, approximately \$0.8 million in subcontractor-related expenses, approximately \$0.2 million of materials-related expenses and approximately \$0.7 million of other expenses. For the three months ended March 31, 2024, our total research and development expenses were approximately \$2.9 million comprised of approximately \$1.5 million of salary and related expenses, approximately \$0.5 million of 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 March 31, 2025 was \$0.6 million, or 21%, compared to the three months ended March 31, 2024. The increase in research and development expenses resulted primarily from the advance in our clinical pipeline.
- Selling, general and administrative expenses were \$2.6 million for the three months ended March 31, 2025, a decrease of

\$0.5 million, or 16%, compared to \$3.1 million for the three months ended March 31, 2024. The decrease resulted primarily from a decrease of \$0.4 million in salary and related expenses and a decrease of \$0.1 million in selling expenses.

- Financial income, net was \$0.4 million for the three months ended March 31, 2025, compared to financial income, net of \$0.1 million for the three months ended March 31, 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 7.50% Senior Secured Convertible Promissory Notes, partially offset by lower interest income on bank deposits and higher exchange rate costs.
- For the three months ended each of March 31, 2025 and March 31, 2024, we recorded a tax benefit of approximately \$(0.1) million. The tax benefit resulted primarily from deferred 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.
- Cash, cash equivalents and short term bank deposits were approximately \$34.7 million at March 31, 2025.
- Net loss for the quarter ended March 31, 2025 was approximately \$3.6 million, or \$0.05 per share, basic and diluted, compared to \$4.6 million, or \$0.06 per share, basic and diluted, for the same period in 2024.

Conference Call and Webcast Information

We will host a conference call today, May 9, 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: Friday, May 9, 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: 13753682
Call me™: <https://tinyurl.com/yey23rkc>

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/3nn9jh5v>
Conference ID: 13753682

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, 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 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.

Investor Contact

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PROTALIX BIOTHERAPEUTICS, INC. CONSOLIDATED BALANCE SHEETS

(U.S. dollars in thousands)

(Unaudited)

March 31, 2025 December 31, 2024

ASSETS

CURRENT ASSETS:

Cash and cash equivalents	\$	19,458	\$	19,760
Short-term bank deposits		15,285		15,070
Accounts receivable – Trade		4,675		2,909
Other assets		1,590		1,096
Inventories		19,506		21,243
Total current assets	\$	60,514	\$	60,078

NON-CURRENT ASSETS:

Funds in respect of employee rights upon retirement	\$	459	\$	462
Property and equipment, net		4,725		4,591
Deferred income tax asset		2,969		2,856
Operating lease right of use assets		5,225		5,430
Total assets	\$	73,892	\$	73,417

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES:

Accounts payable and accruals:				
Trade	\$	4,121	\$	4,533
Other		18,776		19,588
Operating lease liabilities		1,425		1,500
Total current liabilities	\$	24,322	\$	25,621

LONG TERM LIABILITIES:

Liability for employee rights upon retirement	\$	551	\$	559
Operating lease liabilities		3,811		4,026
Total long term liabilities	\$	4,362	\$	4,585

Total liabilities	\$ 28,684	\$ 30,206
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COMMITMENTS

STOCKHOLDERS' EQUITY	45,208	43,211
Total liabilities and stockholders' equity	<u>\$ 73,892</u>	<u>\$ 73,417</u>

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

	<u>Three Months Ended</u>	
	<u>March 31, 2025</u>	<u>March 31, 2024</u>
REVENUES FROM SELLING GOODS	\$ 9,995	\$ 3,677
REVENUES FROM LICENSE AND R&D SERVICES	118	71
TOTAL REVENUE	10,113	3,748
COST OF GOODS SOLD	(8,180)	(2,602)
RESEARCH AND DEVELOPMENT EXPENSES	(3,475)	(2,887)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(2,603)	(3,115)
OPERATING LOSS	(4,145)	(4,856)
FINANCIAL EXPENSES	(6)	(390)
FINANCIAL INCOME	419	513
FINANCIAL INCOME, NET	413	123
LOSS BEFORE TAXES ON INCOME	(3,732)	(4,733)
TAX BENEFIT	113	138
NET LOSS	<u>\$ (3,619)</u>	<u>\$ (4,595)</u>
LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED	<u>\$ (0.05)</u>	<u>\$ (0.06)</u>
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE (basic and diluted)	<u>76,611,980</u>	<u>73,036,569</u>

Logo: https://mma.prnewswire.com/media/999479/Protalix_Biotherapeutics_Logo.jpg

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