Protalix BioTherapeutics Reports Fiscal Year 2024 Financial and Business Results

March 17, 2025

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

CARMIEL, Israel, March 17, 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 fiscal year ended December 31, 2024, and provided a business and clinical update.

"2024 was a record year in revenues from selling goods for Protalix, as we experienced increases in all three of our revenue streams, Chiesi, Pfizer and Brazil," said Dror Bashan, Protalix's President and Chief Executive Officer. "We are pleased with the promising results from our first-in-human study of our gout candidate, PRX-115, in adult volunteers with elevated uric acid levels, and hope to build on this momentum with the goal of initiating a phase II clinical trial in patients with gout during the second half of 2025. At the same time, we continued to evaluate additional pipeline candidates, including PRX-119, for potential further development. Now that our debt is fully repaid and we no longer have outstanding warrants, our balance sheet is stronger and we are well-positioned to continue executing on our strategy through 2025 and beyond."

Fiscal Year 2024 and Recent Business Highlights

Pipeline and Clinical Developments

- 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.
    - The 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.
- In June 2024, we hosted an Investor Day highlighting current treatment landscapes and clinical results for Fabry disease and uncontrolled gout. The event featured presentations from key opinion leaders (KOLs) Aleš Linhart, D.Sc., FESC (Charles University, Prague) and Naomi Schlesinger, M.D. (University of Utah). Our leadership also provided insight into our strategy and future plans. The KOL presentation slides can be found in the Presentations section of the Protalix website: https://ir.protalix.com/news-events/presentations.

Pegunigalsidase alfa

- In December 2024, we and our global development and commercial partner, Chiesi Global Rare Diseases, announced that the European Medicines Agency (EMA) validated the Variation Submission for pegunigalsidase alfa to label a less frequent dosing regimen at a dose of 2 mg/kg administered every four weeks in adult patients with Fabry disease. The variation submission is supported by a revised Population-PK model and new exposure-response analyses, and by the clinical data on pegunigalsidase alfa 2 mg/kg every four weeks from our completed phase III BRIGHT clinical trial of pegunigalsidase alfa (PB-102-F50) and the ongoing extension study.

Corporate Developments

- In September 2024, we repaid in full all of the outstanding principal and interest payable under our then outstanding 7.50% Senior Secured Convertible Promissory Notes due September 2024. The repayment of the convertible notes at maturity was financed entirely with available cash.
- Since December 31, 2024, we issued 908,000 shares of our common stock in connection with the exercise of warrants issued in 2020 generating proceeds equal to approximately $2.1 million from such exercises. The warrants expired on March 11, 2025. Accordingly, no warrants remain outstanding.

Fiscal Year 2024 Financial Highlights

- We recorded revenues from selling goods of $53.0 million for the year ended December 31, 2024, an increase of $12.6 million, or 31%, compared to revenues of $40.4 million for the year ended December 31, 2023. The increase resulted primarily from an increase of $11.8 million in sales to Chiesi, an increase of $0.6 million in sales to Brazil and an increase

of $0.1 million in sales to Pfizer Inc., or Pfizer.

- We recorded revenues from license and R&D services of $0.4 million for the year ended December 31, 2024, a decrease of $24.7 million, or 98%, compared to revenues of $25.1 million for the year ended December 31, 2023. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Company's license and supply agreements with Chiesi Farmaceutici S.p.A., or Chiesi. The revenues from license and R&D services for the year ended December 31, 2023 included the $20.0 million regulatory milestone payment from Chiesi in connection with the approval by the U.S. Food and Drug Administration (FDA) of Elfabrio® granted during that period. The remaining decrease resulted from the completion of our revenue-generating research and development obligations with respect to Elfabrio and, as Elfabrio was approved in the United States and the European Union in May 2023, from the completion of the regulatory processes related to the review of the Biologics License Application (BLA) and the Marketing Authorization Application (MAA) for Elfabrio by the FDA and EMA, respectively. As a result of the completion of the Fabry clinical program in 2023, we expect to generate minimal revenues from license and R&D services other than potential regulatory and commercial milestone payments.
- Cost of goods sold was $24.3 million for the year ended December 31, 2024, an increase of $1.3 million, or 6%, compared to cost of goods sold of $23.0 million for the year ended December 31, 2023. The increase in cost of goods sold was primarily the result of the increase in sales to Chiesi. In addition, during the year ended December 31, 2023 a portion of the costs for certain drug substance sold were recognized as research and development expenses, not cost of goods sold, as such drug substance was produced as part of our research and development activities.
- For the year ended December 31, 2024, our total research and development expenses were approximately $13.0 million comprised of approximately $7.1 million of salary and related expenses, approximately $2.4 million in subcontractor-related expenses, approximately $0.9 million of materials-related expenses and approximately $2.6 million of other expenses. For the year ended December 31, 2023, our total research and development expenses were approximately $17.1 million comprised of approximately $7.8 million of salary and related expenses, approximately $6.3 million in subcontractor-related expenses, approximately $0.6 million of materials-related expenses and approximately $2.4 million of other expenses. Total decrease in research and developments expenses was $4.1 million, or 24%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The decrease in research and development expenses resulted primarily from the completion of our Fabry clinical program and the regulatory processes related to the BLA and MAA review of Elfabrio by the applicable regulatory agencies.
- Selling, general and administrative expenses were $12.2 million for the year ended December 31, 2024, a decrease of $2.8 million, or 19%, from $15.0 million for the year ended December 31, 2023. The decrease resulted primarily from a decrease of $1.8 million in professional fees and of $1.0 million in salaries and related expenses.
- Financial income, net was $0.2 million for the year ended December 31, 2024, compared to financial expenses, net of $1.9 million for the year ended December 31, 2023. The difference resulted primarily from a decrease of approximately $1.4 million in lower interest and related expenses due to the conversion of notes in 2023 and the September 2024 repayment in full of all the outstanding principal and interest payable under the remaining notes, as well as an increase in interest income, net of $0.7 million.
- For the year ended December 31, 2024, we recorded income taxes of approximately $1.2 million, an increase of $0.9 million, or 300%, compared to income taxes of $0.3 million for the year ended December 31, 2023. The income taxes resulted primarily from the provision for current taxes on income mainly derived from GILTI income mainly in respect of Section 174 of the U.S. Tax Cuts and Jobs Act, 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 $34.8 million at December 31, 2024.
- Net income for the year ended December 31, 2024 was approximately $2.9 million, or $0.04 per share, basic and diluted, compared to $8.3 million or $0.12 per share, basic, and $0.09 per share, diluted, for the same period in 2023.

Conference Call and Webcast Information

We will host a conference call today, March 17, 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: Monday, March 17, 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: 13752080
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/yjfybd5t
Conference ID: 13752080

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)

	December 31,	
	2023	**2024**

ASSETS

CURRENT ASSETS:		
Cash and cash equivalents	$ 23,634	$ 19,760
Short-term bank deposits	20,926	15,070
Accounts receivable – Trade	5,272	2,909
Other assets	1,055	1,096
Inventories	19,045	21,243
Total current assets	$ 69,932	$ 60,078
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 528	$ 462
Property and equipment, net	4,973	4,591
Deferred income tax asset	3,092	2,856
Operating lease right of use assets	5,909	5,430
Total assets	$ 84,434	$ 73,417
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,320	$ 4,533
Other	19,550	19,588
Operating lease liabilities	1,409	1,500
Convertible notes	20,251	—
Total current liabilities	$ 45,530	$ 25,621
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	714	$ 559
Operating lease liabilities	4,621	4,026
Total long term liabilities	$ 5,335	$ 4,585
Total liabilities	$ 50,865	$ 30,206
COMMITMENTS		
STOCKHOLDERS' EQUITY		
Common Stock, $0.001 par value: Authorized - as of December 31, 2023 and 2024, 185,000,000 shares; issued and outstanding - as of December 31, 2023 and 2024, 72,952,124 and 75,850,275 shares, respectively	73	76
Additional paid-in capital	415,045	421,528
Accumulated deficit	(381,549)	(378,393)
Total stockholders' equity	33,569	43,211
Total liabilities and stockholders' equity	$ 84,434	$ 73,417

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

	Year Ended December 31,		
	2022	**2023**	**2024**
REVENUES FROM SELLING GOODS	$ 25,292	$ 40,418	$ 52,981
REVENUES FROM LICENSE AND R&D SERVICES	22,346	25,076	418
TOTAL REVENUE	47,638	65,494	53,399
COST OF GOODS SOLD	(19,592)	(22,982)	(24,319)
RESEARCH AND DEVELOPMENT EXPENSES	(29,349)	(17,093)	(12,970)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(11,711)	(14,959)	(12,193)
OPERATING INCOME (LOSS)	(13,014)	10,460	3,917

FINANCIAL EXPENSES	(2,529)	(3,180)	(1,062)
FINANCIAL INCOME	1,146	1,286	1,299
FINANCIAL INCOME (EXPENSES), NET	(1,383)	(1,894)	237
INCOME (LOSS) BEFORE TAXES ON INCOME	(14,397)	8,566	4,154
TAXES ON INCOME	(530)	(254)	(1,222)
NET INCOME (LOSS)	$ (14,927)	$ 8,312	$ 2,932
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:			
BASIC	$ (0.31)	$ 0.12	$ 0.04
DILUTED	$ (0.31)	$ 0.09	$ 0.04
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:			
BASIC	48,472,159	67,512,527	72,530,698
DILUTED	48,472,159	82,424,016	81,057,176

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