Protalix BioTherapeutics Reports Fiscal Year 2023 Financial and Business Results

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

CARMIEL, Israel, March 14, 2024 /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, 2023, and provided a business update.

"2023 was a significant year for Protalix, as we received regulatory approvals of Elfabrio for the treatment of adult patients with Fabry disease and advanced our growing pipeline," said Dror Bashan, Protalix's President and Chief Executive Officer. "As the second drug produced through our proven protein expression platform, Elfabrio's approval is a welcome milestone for Fabry disease patients and their families. Our commercial partner Chiesi Global Rare Diseases is continuing to position Elfabrio for global success, with launches underway in the United States, the European Union, the UK and additional markets where approvals were granted. As we continue to provide Chiesi with operational support for its activities, we have turned our attention to developing our innovative pipeline. For example, PRX-115, our proprietary recombinant PEGylated uricase for the treatment of severe gout, is currently being studied in a first-in-human phase I clinical trial. We anticipate that results from the trial will be published in the second quarter of 2024. As a company powered by a professional team and solid financials, and with the potential for revenue growth, we are poised for an exciting future and look forward to making a positive impact on patients' lives and delivering long-term value to our stockholders."

Fiscal Year 2023 and Recent Business Highlights

Regulatory and Commercial Advancements

The Company, together with its development and commercialization partner, Chiesi Global Rare Diseases (Chiesi), a business unit of the Chiesi Group, gained marketing authorizations in the United States, the European Union, the UK, Switzerland and Israel for Elfabrio® (pegunigalsidase alfa), a PEGylated recombinant human α-Galactosidase-A enzyme, for the treatment of adult patients with confirmed Fabry disease. Elfabrio is administered via intravenous infusion at a dose of 1 mg/kg every two weeks.

- On May 5, 2023, the Company announced that the European Commission (EC) granted marketing authorization to Elfabrio in the European Union for the treatment of adult patients with Fabry disease.
- On May 10, 2023, the Company announced that the U.S. Food and Drug Administration (FDA) approved Elfabrio in the United States for the treatment of adult patients with Fabry disease.
- On August 15, 2023, Chiesi announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted marketing authorization for Elfabrio in Great Britain for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease.
- On September 11, 2023, Swissmedic, the national authorization and supervisory authority for drugs and medical products in Switzerland, announced the approval of Elfabrio in Switzerland for long-term enzyme replacement therapy in adult patients with a confirmed diagnosis of Fabry disease.
- In January 2024, the Israeli Ministry of Health granted principle approval of Elfabrio for adult patients with a confirmed diagnosis of Fabry disease.

The FDA approval triggered a $20.0 million milestone payment from Chiesi. In addition, the Company generated $17.5 million from sales of Elfabrio to Chiesi during 2023 post-regulatory approval, as Chiesi is building its inventory and recruiting commercial patients in the United States and Europe.

Clinical Developments

In March 2023, the first patient was dosed in the Company's First in Human (FIH) Phase I clinical trial of PRX–115, a recombinant PEGylated uricase product candidate under development as a potential treatment for severe gout. The FIH trial is a double-blind, placebo-controlled, single ascending dose study designed to evaluate the safety, pharmacokinetics, pharmacodynamics and immunogenicity of PRX–115 in approximately 56 patients with

elevated uric acid levels (>6.0 mg/dL) and no previous exposure to PEGylated uricase. The study, which is fully-enrolled, is being conducted at the New Zealand Clinical Research (NZCR) under the New Zealand Medicines and Medical Devices Safety Authority (MedSafe) and the Health and Disability Ethics Committee (HDEC) guidelines. The Company anticipates that preliminary results from the study will be published in the second quarter of 2024.

Corporate Developments

On September 14, 2023, Eliot Richard Forster, Ph.D. began his tenure as Chairman of the Board of Directors, replacing former Chairman Zeev Bronfeld, who retired for personal reasons.

Fiscal Year 2023 Financial Highlights

- The Company recorded revenues from selling goods of $40.4 million for the year ended December 31, 2023, an increase of $15.1 million, or 60%, compared to revenues of $25.3 million for the year ended December 31, 2022. The increase resulted primarily from an increase of $14.1 million in sales of Elfabrio drug product to Chiesi, following the approvals by the FDA and the European Medicines Agency (EMA) of Elfabrio, an increase of $0.1 million in sales to Pfizer Inc., or Pfizer, and of $0.9 million in sales to Brazil, resulting from timing differences.
- The Company recorded revenues from license and R&D services of $25.1 million for the year ended December 31, 2023, an increase of $2.8 million, or 13%, compared to revenues of $22.3 million for the year ended December 31, 2022. The increase resulted from the $20.0 million regulatory milestone payment from Chiesi in connection with the FDA approval of Elfabrio which was partially offset by a decrease of $17.2 million in revenues recognized in connection with the R&D performance obligation under the Chiesi Agreements as the Company has completed the phase III clinical program thereunder. Revenues from license and R&D services represent primarily the revenues the Company recognized for services provided under the Chiesi Agreements.
- Cost of goods sold was $23.0 million for the year ended December 31, 2023, an increase of $3.4 million, or 17%, compared to cost of goods sold of $19.6 million for the year ended December 31, 2022. The increase in cost of goods sold was primarily the result of the increase in sales of goods to Chiesi, Brazil and to Pfizer. Sales to Chiesi included certain drug substance costs which had already been recognized as research and development expenses as it was produced as part of research and development activities. Accordingly, the related cost of goods sold does not include the costs of such drug substance.
- For the year ended December 31, 2023, the Company's total research and development expenses were approximately $17.1 million, comprised of approximately $6.3 million in subcontractor-related expenses, approximately $7.8 million of salary and related expenses, approximately $0.6 million of materials-related expenses and approximately $2.4 million of other expenses. For the year ended December 31, 2022, the Company's total research and development expenses were approximately $29.3 million, comprised of approximately $17.8 million in subcontractor-related expenses, approximately $7.3 million of salary and related expenses, approximately $1.4 million of materials-related expenses and approximately $2.8 million of other expenses. Total decrease in research and developments expenses was $12.2 million, or 42%, for the year ended December 31, 2023 compared to the year ended December 31, 2022. The decrease in research and development expenses resulted primarily from a $11.5 million decrease in subcontractor-related expenses in connection with the PRX-102 clinical trials, and a $0.8 million decrease in materials-related expenses.
- Selling, general and administrative expenses were $15.0 million for the year ended December 31, 2023, an increase of $3.3 million, or 28%, from $11.7 million for the year ended December 31, 2022. The increase resulted primarily from an increase of approximately $2.3 million in one-time cash bonuses, share-based compensation and salary and salary-related expenses, as well as an increase of $0.3 million in travel, conferences and employee training expenses.
- Financial expense, net was $1.9 million for the year ended December 31, 2023, an increase of $0.5 million, or 36%, compared to financial expenses of $1.4 million for the year ended December 31, 2022. The increase was primarily due to a decrease of $0.9 million in income related to exchange rates as well as an increase in interest expenses of $0.7 million which was partially offset by a gain recognized due to conversions of a portion of the 2024 Notes of $0.4 million and a $0.6 million increase in interest income.
- For the year ended December 31, 2023, the Company recorded income taxes of approximately $0.3 million, a decrease of $0.2 million, or 40%, compared to tax expenses of $0.5 million for the year ended December 31, 2022. The income taxes resulted primarily from the provision for current taxes on income mainly derived from U.S. taxable global intangible low-taxed income (GILTI) mainly in respect of Section 174 of the U.S. Tax Cuts and Jobs Act (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. The net income taxes gives effect to a valuation allowance release equal to approximately $3.1 million.
- Cash, cash equivalents and short-term bank deposits were approximately $44.6 million at December 31, 2023.
- Net income for the year ended December 31, 2023 was approximately $8.3 million, or $0.12 per share, basic, and $0.09 per share, diluted, compared to a net loss of $14.9 million, or $0.31 per share, basic and diluted, for the same period in 2022.

Conference Call and Webcast Information

The Company will host a conference call today, March 14, 2024 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, March 14, 2024
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: 13744193
Call me™: https://tinyurl.com/4pkhcxcj

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 Company's website and will be available via the following links:

Company Link: https://protalixbiotherapeutics.gcs-web.com/events0
Webcast Link: https://tinyurl.com/mumnf9da
Conference ID: 13744193

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 Company's 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 severe gout; PRX–119, a plant cell-expressed long action 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 "expect," "anticipate," "believe," "estimate," "project," "may," "plan," "will," "would," "should" and "intend," 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; 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 potential commercial value 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 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 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 Inc., or Pfizer, 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 our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; risks relating to changes to interim, topline 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; and 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,	
	2022	**2023**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,111	$ 23,634
Short-term bank deposits	5,069	20,926
Accounts receivable – Trade	4,586	5,272
Other assets	1,310	1,055
Inventories	16,804	19,045
Total current assets	$ 44,880	$ 69,932
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,267	$ 528
Property and equipment, net	4,553	4,973
Deferred income tax asset	—	3,092
Operating lease right of use assets	5,087	5,909
Total assets	$ 55,787	$ 84,434
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,862	$ 4,320
Other	12,271	19,550
Operating lease liabilities	1,118	1,409
Contracts liability	13,178	—
Convertible notes	—	20,251
Total current liabilities	$ 32,429	$ 45,530
LONG TERM LIABILITIES:		
Convertible notes	$ 28,187	
Liability for employee rights upon retirement	1,642	$ 714
Operating lease liabilities	4,169	4,621
Total long term liabilities	$ 33,998	$ 5,335
Total liabilities	$ 66,427	$ 50,865

COMMITMENTS		
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)		
Common Stock, $0.001 par value: Authorized - as of December 31, 2022 and 2023, 144,000,000 and 185,000,000 shares, respectively; issued and outstanding - as of December 31, 2022 and 2023, 53,790,167 and 72,952,124 shares, respectively	54	73
Additional paid-in capital	379,167	415,045
Accumulated deficit	(389,861)	(381,549)
Total stockholders' equity (capital deficiency)	(10,640)	33,569
Total liabilities and stockholders' equity (net of capital deficiency)	$ 55,787	$ 84,434

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

	Year Ended December 31,		
	2021	**2022**	**2023**
REVENUES FROM SELLING GOODS	$ 16,749	$ 25,292	$ 40,418
REVENUES FROM LICENSE AND R&D SERVICES	21,601	22,346	25,076
TOTAL REVENUE	38,350	47,638	65,494
COST OF GOODS SOLD	(16,349)	(19,592)	(22,982)
RESEARCH AND DEVELOPMENT EXPENSES	(29,734)	(29,349)	(17,093)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(12,729)	(11,711)	(14,959)
OPERATING INCOME (LOSS)	(20,462)	(13,014)	10,460
FINANCIAL EXPENSES	(7,521)	(2,529)	(3,180)
FINANCIAL INCOME	401	1,146	1,286
FINANCIAL EXPENSES, NET	(7,120)	(1,383)	(1,894)
INCOME (LOSS) BEFORE TAXES ON INCOME	(27,582)	(14,397)	8,566
TAXES ON INCOME	—	(530)	(254)
NET INCOME (LOSS) FOR THE PERIOD	$ (27,582)	$ (14,927)	$ 8,312
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:			
BASIC	$ (0.62)	$ (0.31)	$ 0.12
DILUTED	$ (0.62)	$ (0.31)	$ 0.09
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:			
BASIC	44,140,233	48,472,159	67,512,527
DILUTED	44,140,233	48,472,159	82,424,016

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