Protalix BioTherapeutics Reports First Quarter 2024 Financial and Business Results

May 10, 2024

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

CARMIEL, Israel, May 10, 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 quarter ended March 31, 2024, and provided a business and clinical update.

"We are pleased to announce that initial top-line results from the first seven cohorts of the first-in-human phase I clinical trial of our recombinant uricase candidate, PRX-115, are encouraging, enabling us to expand into an eighth cohort and to begin planning a phase II trial," said Dror Bashan, Protalix's President and Chief Executive Officer. "We will analyze and announce the full results from the expanded trial following the completion of the new cohort. We believe that our strong cash position is sufficient to enable the repayment of our convertible notes due September 2024, and for our ongoing operations."

First Quarter 2024 and Recent Business Highlights

Clinical Developments

The PRX-115 trial is a double blind, placebo-controlled, single ascending dose (SAD), First-in-Human phase I clinical trial of PRX-115 for the potential treatment of uncontrolled gout (the "FIH Study") that the Company designed to evaluate the safety, pharmacokinetics (PK) and pharmacodynamics (PD; reduction of uric acid) following single dose of PRX-115 in subjects with elevated uric acid levels. Of the 56 randomized subjects enrolled in the study across seven cohorts, 42 subjects were treated with PRX–115 and 14 subjects were treated with a placebo.

After a review of the initial positive top–line results from the seven cohorts, and following the review and acceptance of the safety data from cohort 7 by the safety and monitoring committee for dose escalation for the FIH Study, the Company decided to expand the study by adding an eighth cohort of eight new subjects to analyze a higher dose and its potential to result in increased exposure time. In addition to the expansion of the FIH Study, the Company also decided to commence preparations for a phase II clinical trial of PRX-115.

Key preliminary results from the FIH Study are as follows:

- Exposure to PRX–115 increased in a dose–dependent manner.
- PRX–115 rapidly reduced plasma uric acid concentrations to below 6.0 mg/dL over time following a single administration. The effect of PRX–115 on plasma uric acid concentrations and the duration of response was found to be dose dependent.
- PRX–115 was well-tolerated. Twenty-six percent (11/42) of the subjects treated with PRX–115 in the first seven cohorts reported study drug-related adverse events (AEs), the majority being mild to moderate and transient in nature. One subject in cohort 2 experienced an anaphylactic reaction immediately following the commencement of the infusion, and the reaction was fully resolved. There were no other serious AEs reported in the study, and no AEs were reported in the highest doses, cohorts 6 and 7.

Research & Development

In addition, to PRX-115 and PRX-119, the Company's plant cell-expressed PEGylated recombinant human DNase I product candidate being designed to elongate half-life in the circulation for NETs-related diseases, the Company is focusing its research & development efforts on early-stage development assets to build its product development pipeline.

First Quarter 2024 Financial Highlights

- The Company recorded revenues from selling goods of $3.7 million for the three months ended March 31, 2024, a decrease of $1.4 million, or 27%, compared to revenues of $5.1 million for the three months ended March 31, 2023. The decrease resulted primarily from a decrease of $1.1 million in sales to Pfizer, and of $0.3 million in sales to Brazil. The decreases resulted primarily from the timing of delivery.
- The Company recorded revenues from license and R&D services of $0.1 million for the three months ended March 31, 2024, a decrease of $4.4 million, or 98%, compared to revenues of $4.5 million for the three months ended March 31, 2023. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements. The decrease resulted primarily from the completion of the Company's 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 BLA and the MAA and for Elfabrio by the FDA and EMA, respectively.

- Cost of goods sold was $2.6 million for the three months ended March 31, 2024, a decrease of $0.5 million, or 16%, from cost of goods sold of $3.1 million for the three months ended March 31, 2023. The decrease in cost of goods sold was primarily the result of the decrease in sales to Pfizer and to Brazil.

- For the three months ended March 31, 2024, the Company's total research and development expenses were approximately $2.9 million, comprised of approximately $0.5 million in subcontractor-related expenses, approximately $1.5 million of salary and 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, 2023, the Company's total research and development expenses were approximately $5.8 million comprised of approximately $3.5 million of subcontractor-related expenses, approximately $1.5 million of salary and related expenses, approximately $0.1 million of materials-related expenses and approximately $0.7 million of other expenses. Total decrease in research and developments expenses for the three months ended March 31, 2024 was $2.9 million, or 50%, compared to the three months ended March 31, 2023. The decrease in research and development expenses primarily resulted from the completion of the Company's 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 $3.1 million for the three months ended March 31, 2024 and for the three months ended March 31, 2023.

- Financial income, net were $0.1 million for the three months ended March 31, 2024, compared to financial expenses, net of $0.5 million for the three months ended March 31, 2023. The change resulted primarily from higher interest income on bank deposits and lower notes interest expenses due to note conversions executed in 2023.

- In the three months ended March 31, 2024, the Company recorded a tax benefit of approximately $(0.1) million, compared to income taxes of $0.2 million for the three months ended March 31, 2023. Income taxes recorded are 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.

- Cash, cash equivalents and short-term bank deposits were approximately $48.5 million at March 31, 2024.

- Net loss for the three months ended March 31, 2024 was approximately $4.6 million, or $0.06 per share, basic and diluted, compared to a net loss of $3.1 million, or $0.05 per share, basic and diluted, for the same period in 2023.

Conference Call and Webcast Information

The Company will host a conference call today, May 10, 2024, at 8:30 am EDT to review the financial results and provide a business and clinical 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 10, 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:	13745800
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/3r8rks24
Conference ID:	13745800

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 uncontrolled 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, 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 for 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	March 31, 2024	December 31, 2023

ASSETS

CURRENT ASSETS:		
Cash and cash equivalents	$ 27,209	$ 23,634
Short-term bank deposits	21,278	20,926
Accounts receivable – Trade	3,759	5,272
Other assets	812	1,055
Inventories	22,346	19,045
Total current assets	$ 75,404	$ 69,932
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 531	$ 528
Property and equipment, net	4,781	4,973
Deferred income tax asset	3,230	3,092
Operating lease right of use assets	5,879	5,909
Total assets	$ 89,825	$ 84,434
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,146	$ 4,320
Other	18,770	19,550
Operating lease liabilities	1,453	1,409
Contracts liability	11,039	-
Convertible notes	20,420	20,251
Total current liabilities	$ 54,828	$ 45,530
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 712	$ 714
Operating lease liabilities	4,499	4,621
Total long term liabilities	$ 5,211	$ 5,335
Total liabilities	$ 60,039	$ 50,865
COMMITMENTS		
STOCKHOLDERS' EQUITY	29,786	33,569
Total liabilities and stockholders' equity	$ 89,825	$ 84,434

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

	Three Months Ended	
	March 31, 2024	March 31, 2023
REVENUES FROM SELLING GOODS	$ 3,677	$ 5,066
REVENUES FROM LICENSE AND R&D SERVICES	71	4,522
TOTAL REVENUE	3,748	9,588
COST OF GOODS SOLD	(2,602)	(3,085)
RESEARCH AND DEVELOPMENT EXPENSES	(2,887)	(5,847)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(3,115)	(3,115)
OPERATING LOSS	(4,856)	(2,459)
FINANCIAL EXPENSES	(390)	(649)
FINANCIAL INCOME	513	172
FINANCIAL INCOME (EXPENSES), NET	123	(477)
LOSS BEFORE TAX BENEFIT (TAXES ON INCOME)	(4,733)	(2,936)
TAX BENEFIT (TAXES ON INCOME)	138	(195)
NET LOSS FOR THE PERIOD	$ (4,595)	$ (3,131)
LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED	$ (0.06)	$ (0.05)

WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE (Basic and Diluted):	73,036,569	57,480,009

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