Protalix BioTherapeutics Reports Third Quarter 2024 Financial and Business Results

November 14, 2024

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

CARMIEL, Israel, Nov. 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 quarter ended September 30, 2024, and provided a business and clinical update.

"We are pleased to report that all eight cohorts of our phase I first-in-human study of PRX-115, our recombinant uricase candidate being developed for the treatment of uncontrolled gout, are now complete," said Dror Bashan, Protalix's President and Chief Executive Officer. "Preliminary results from this study, being presented today and this week in a late-breaking poster at ACR Convergence 2024, are encouraging and demonstrate the potential of PRX-115 to be a promising uric-acid lowering treatment option for individuals with gout. We are actively planning a phase II clinical trial of PRX-115 in gout patients and expect to initiate the study in the second half of 2025."

Third Quarter 2024 and Recent Business Highlights

Pipeline Developments

The Company's PRX–115 trial is a double blind, placebo-controlled, single ascending dose (SAD), First-in-Human phase I clinical trial evaluating PRX–115 for the potential treatment of gout. The study is designed to evaluate the safety, pharmacokinetics (PK) and pharmacodynamics (PD; reduction of uric acid) following a single dose of PRX-115 in subjects with elevated uric acid levels. In the study, 64 randomized subjects were enrolled across eight cohorts, each composed of eight subjects (six active and two placebo). All of the subjects completed the study. At this time, the data is locked and is currently being analyzed.

Preliminary results from the full study are as follows:

- Exposure to PRX-115 increased in a dose-dependent manner. PRX-115 levels were observed in plasma for up to 12 weeks from subjects in cohorts 6, 7 and 8.
- In all tested doses, a single dose of PRX-115 rapidly reduced plasma uric acid levels. The effect and duration of response were found to be dose dependent. Following a single dose, mean plasma uric acid levels remained below 6.0 mg/dL for up to 12 weeks at the highest dose levels.
- PRX–115 was found to be well-tolerated with only 25% of the subjects treated with PRX–115 in the study (12/48) having reported study drug-related adverse events, the majority of which were mild to moderate and transient in nature. One subject experienced an anaphylactic reaction immediately following the start of infusion that was resolved completely. No other serious adverse events were reported in the study.

The preliminary results demonstrate that PRX-115 may 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.

These preliminary results are being 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. The accepted abstract can be accessed on the ACR Convergence 2024 website at https://acrabstracts.org/abstract/prolonged-plasma-urate-lowering-after-a-single-intravenous-administration-of-prx-115-a-novel-pegylated-uricase-in-participants-with-elevated-urate-levels/. A copy of the poster will be made available on the Protalix website.

Corporate Developments

- In September 2024, the Company repaid in full all of the outstanding principal and interest payable under its 7.50% Senior Secured Convertible Promissory Notes due September 2024. The repayment of the convertible notes at maturity was financed entirely with available cash.

Third Quarter 2024 Financial Highlights

- The Company recorded revenues from selling goods of $17.8 million during the three months ended September 30, 2024, an increase of $7.6 million, or 75%, compared to revenues of $10.2 million for the three months ended September 30, 2023. The increase resulted primarily from an increase of $6.8 million in sales to Chiesi Farmaceutici S.p.A. ("Chiesi"), and an increase of $1.1 million in sales to Pfizer Inc. ("Pfizer"), partially offset by a decrease of $0.3 million in sales to Brazil.

- The Company recorded revenues from license and R&D services of $0.1 million for the three months ended September 30, 2024, a decrease of $0.1 million, or 50%, compared to revenues of $0.2 million for the three months ended September 30, 2023. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with our license agreements with Chiesi.
- Cost of goods sold was $8.4 million for the three months ended September 30, 2024, an increase of $3.5 million, or 71%, from cost of goods sold of $4.9 million for the three months ended September 30, 2023. The increase in cost of goods sold was primarily the result of an increase in sales to Chiesi and Pfizer.
- For the three months ended September 30, 2024, our total research and development expenses were approximately $3.0 million comprised of approximately $0.6 million in subcontractor-related expenses, approximately $1.6 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.6 million of other expenses. For the three months ended September 30, 2023, our total research and development expenses were approximately $3.7 million comprised of approximately $1.0 million of subcontractor-related expenses, approximately $1.9 million of salary and related expenses, approximately $0.2 million of materials-related expenses and approximately $0.6 million of other expenses.

  Total decrease in research and developments expenses for the three months ended September 30, 2024 was $0.7 million, or 19%, compared to the three months ended September 30, 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 review of the Elfabrio Biologics License Application (BLA) in the United States and the Marketing Authorization Application (MAA) in the European Union by the applicable regulatory agencies.

- Selling, general and administrative expenses were $2.6 million for the three months ended September 30, 2024, a decrease of $1.1 million, or 30%, compared to $3.7 million for the three months ended September 30, 2023. The decrease resulted primarily from a decrease of $0.5 million in salary and related expenses and a decrease of $0.4 million in professional fees.
- Financial expenses, net was $0.1 million for the three months ended September 30, 2024, compared to financial income, net of $0.2 million for the three months ended September 30, 2023. The difference resulted primarily from lower interest income on bank deposits, higher exchange rate costs 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 2024 Notes.
- For the three months ended September 30, 2024, we recorded income taxes of approximately $0.6 million, compared to income taxes of $0.1 million for the three months ended September 30, 2023. Income taxes recorded are primarily the result of tax expenses in respect of Section 174 of the U.S. Tax Cuts and Jobs Act, which was enacted in December 2017.
- Cash and cash equivalents were approximately $27.4 million at September 30, 2024.
- Net income for the three months ended September 30, 2024 was approximately $3.2 million, or $0.04 per share, basic, and $0.03 per share, diluted, compared to a net loss of $1.9 million, or $0.03 per share, basic, and $0.04 per share, diluted, for the same period in 2023.
- Since the end of the quarter ended September 30, 2024, the Company collected approximately $3.9 million from sales to Chiesi.

Conference Call and Webcast Information

The Company will host a conference call today, November 14, 2024 at 8:30 a.m. EST, 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, November 14, 2024
Time: 8:30 a.m. Eastern Standard Time (EST)
Toll Free: 1-877-423-9813
International: 1-201-689-8573
Israeli Toll Free: 1-809-406-247
Conference ID: 13749493
Call me™: https://tinyurl.com/2n9fhumh

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:
Company Link: https://ir.protalix.com/news-events/events
Webcast Link: https://tinyurl.com/3be68pkw
Conference ID: 13749493

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 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; 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)

	September 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 27,409	$ 23,634
Short-term bank deposits		20,926
Accounts receivable – Trade	2,195	5,272
Other assets	1,050	1,055
Inventories	17,199	19,045
Total current assets	$ 47,853	$ 69,932
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 561	$ 528
Property and equipment, net	4,648	4,973

Deferred income tax asset	2,856	3,092
Operating lease right of use assets	5,645	5,909
Total assets	$ 61,563	$ 84,434
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,135	$ 4,320
Other	19,577	19,550
Operating lease liabilities	1,508	1,409
Convertible notes	-	20,251
Total current liabilities	$ 24,220	$ 45,530
LONG TERM LIABILITIES:		
Liability for employee rights upon retirement	$ 730	$ 714
Operating lease liabilities	4,176	4,621
Total long term liabilities	$ 4,906	$ 5,335
Total liabilities	$ 29,126	$ 50,865
COMMITMENTS		
STOCKHOLDERS' EQUITY	32,437	33,569
Total liabilities and stockholders' equity	$ 61,563	$ 84,434

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

	Nine Months Ended		Three Months Ended	
	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
REVENUES FROM SELLING GOODS	$ 34,820	$ 30,309	$ 17,839	$ 10,168
REVENUES FROM LICENSE AND R&D SERVICES	361	24,699	120	177
TOTAL REVENUE	35,181	55,008	17,959	10,345
COST OF GOODS SOLD	(20,433)	(14,126)	(8,375)	(4,893)
RESEARCH AND DEVELOPMENT EXPENSES	(8,846)	(13,991)	(2,998)	(3,669)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(9,194)	(10,816)	(2,595)	(3,670)
OPERATING INCOME (LOSS)	(3,292)	16,075	3,991	(1,887)
FINANCIAL EXPENSES	(1,056)	(2,406)	(299)	(460)
FINANCIAL INCOME	1,186	1,323	151	628
FINANCIAL INCOME (EXPENSES), NET	130	(1,083)	(148)	168
INCOME (LOSS) BEFORE TAXES ON INCOME	(3,162)	14,992	3,843	(1,719)
TAXES ON INCOME	(400)	(636)	(607)	(133)
NET INCOME (LOSS) FOR THE PERIOD	$ (3,562)	$ 14,356	$ 3,236	$ (1,852)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK:				
BASIC	$ (0.05)	$ 0.22	$ 0.04	$ (0.03)
DILUTED	$ (0.05)	$ 0.16	$ 0.03	$ (0.04)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE:				
BASIC	73,301,091	65,811,506	73,549,745	72,281,681
DILUTED	73,301,091	81,040,281	81,217,068	83,782,679

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