Protalix BioTherapeutics Reports Third Quarter 2022 Financial and Business Results

November 14, 2022

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

CARMIEL, Israel, Nov. 14, 2022 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: PLX) (TASE: 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 third quarter ended September 30, 2022 and provided a business update on recent corporate and regulatory developments.

"We are happy we have reached a significant milestone for our company with the recent BLA resubmission to the FDA," said Dror Bashan, Protalix's President and Chief Executive Officer. "We believe PRX-102, if approved, has the potential to significantly impact patients living with this rare, life-threatening genetic disease. As we approach potential approval and commercialization of PRX-102, we affirm our dedication to our mission of bringing new medicines to patients with serious diseases. We are grateful to our team members and external partners for their continued commitment to this program."

2022 Third Quarter and Recent Business Highlights

Regulatory Updates

- On November 9, 2022, the Company, together with its development and commercialization partner for PRX–102, Chiesi Farmaceutici S.p.A. ("Chiesi"), resubmitted a biologics license application (BLA) to the U.S. Food and Drug Administration (FDA) for PRX-102 (pegunigalsidase alfa) for the treatment of adult patients with Fabry disease. The BLA re-submission included the final two year analyses of our phase III *BALANCE* clinical trial, which analyses were completed in July 2022, and long-term data from our open-label extension study of PRX–102 in adult patients treated with a 2 mg/kg every four weeks dosage of PRX 102. The initial BLA included a comprehensive set of preclinical, clinical and manufacturing data compiled from our completed phase I/II clinical trial of PRX 102, including the related extension study, interim clinical data from our phase III *BRIDGE* clinical trial and safety data from our on-going clinical studies of PRX 102 in adult patients receiving 1 mg/kg every two weeks.

Third Quarter 2022 Financial Highlights

- The Company recorded revenues from selling goods of $8.8 million during the three months ended September 30, 2022, an increase of $4.3 million, or 96%, compared to revenues of $4.5 million for the three months ended September 30, 2021. An increase of $3.4 million in sales to Pfizer Inc., resulting from timing differences, and an increase of $2.4 million in sales to Chiesi was partially offset by a decrease of $1.5 million in sales to Brazil resulting from timing differences.
- Revenue from licenses and R&D services for the three months ended September 30, 2022 were $5.4 million, a decrease of $2.1 million, or 28%, compared to revenues of $7.5 million for the three months ended September 30, 2021. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the Chiesi Agreements.
- Cost of goods sold was $7.1 million for the three months ended September 30, 2022, an increase of $3.4 million, or 91%, from cost of goods sold of $3.7 million for the three months ended September 30, 2021. The increase in cost of goods sold was primarily the result of the increase in sales of goods.
- For the three months ended September 30, 2022, our total research and development expenses were approximately $7.4 million comprised of approximately $4.9 million in subcontractor-related expenses, approximately $1.7 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, 2021, our total research and development expenses were approximately $7.3 million comprised of approximately $4.8 million in subcontractor-related expenses, approximately $1.6 million of salary and related expenses, approximately $0.1 million of materials-related expenses and approximately $0.8 million of other expenses. Total increase in research and developments expenses was $0.1 million, or 1%, for the three months ended September 30, 2022 compared to the three months ended September 30, 2021.
- Selling, general and administrative expenses were $2.8 million for the three months ended September 30, 2022, a decrease of $0.2 million, or 7%, compared to $3.0 million for the three months ended September 30, 2021. The decrease was primarily due to a decrease in salary related and selling costs.
- Financial expenses, net were $0.4 million for the three months ended September 30, 2022, compared to $2.3 million for the three months ended September 30, 2021. The decrease resulted primarily from lower interest and debt amortization costs due to a decrease in our outstanding notes from an aggregate principal amount of $57.92 million of 2021 Notes to an aggregate principal amount of $28.75 million of 2024 Notes, and an increase in the exchange rate of New Israeli Shekels for U.S. Dollars over the period.
- Cash, cash equivalents and short-term bank deposits were approximately $20.8 million at September 30, 2022.
- Net loss for the three months ended September 30, 2022 was approximately $3.6 million, or $0.07 per share, basic and diluted, compared to a net loss of approximately $4.2 million, or $0.09 per share, basic and diluted, for the same period in 2021.

Conference Call and Webcast Information

The Company will host a conference call today, November 14, 2022, at 8:30 a.m. Eastern Standard Time, to review the corporate and regulatory developments, which will also be available by webcast. To participate in the conference call, please dial the following numbers prior to the start of the call:

Conference Call Details:

Monday, November 14, 2022, 8:30 a.m. Eastern Standard Time (EST)
Domestic: 1-877-423-9813
International: 1-201-689-8573
Conference ID: 13734038

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/2s6sdx5e
Conference ID: 13734038

Please access the websites at least 15 minutes ahead of the conference to register, download and install any necessary audio software.

The conference call will be available for replay 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. Protalix was 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. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved by the FDA in May 2012 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights.

Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified stabilized version of the recombinant human α–Galactosidase–A protein for the treatment of Fabry disease; alidornase alfa or PRX–110, for the treatment of various human respiratory diseases or conditions; 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. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

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: the risk that the FDA will find that the resubmitted BLA for PRX–102 is incomplete or not properly reviewable at the time of submission and, accordingly, refuse to file the resubmitted BLA or request additional information; risks related to the acceptance by the FDA of the resubmitted BLA for PRX–102, and the timing, progress and likelihood of final approval by the FDA and European Medicines Agency (EMA) of the resubmitted BLA and of a Marketing Authorization Application, respectively, for PRX–102 and, if approved, whether the use of PRX–102 will be commercially successful; likelihood that the FDA, EMA or other applicable health regulatory authorities will approve an alternative dosing regimen; risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; failure or delay in the commencement or completion of our preclinical studies and clinical trials for our other product candidates, 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; and inability to monitor patients adequately during or after treatment; the risk that the FDA, EMA, or other foreign regulatory authorities may not accept or approve a marketing application we file for any of our other product candidates, and other risks relating to the review process; risks associated with the novel coronavirus disease, or COVID–19, outbreak and variants, which may adversely impact our business, preclinical studies and clinical trials; 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; the risk that the results of the clinical trials of our product candidates will not support the applicable claims of safety or efficacy, or that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks related to our ability to maintain and manage our relationship with our collaborators, distributors or partners; 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; 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; delays in our preparation and filing of applications for regulatory approval; 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 and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; risks related to our expectations with respect to the potential commercial value of our product and product candidates; 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. 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

Chuck Padala, Managing Director
LifeSci Advisors
646-627-8390
chuck@lifesciadvisors.com

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PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	September 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,720	$ 38,985
Short-term bank deposits	10,091	-
Accounts receivable – Trade	8,651	3,442
Other assets	1,736	1,285
Inventories	14,562	17,954
Total current assets	$ 45,760	$ 61,666
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,418	$ 2,077
Property and equipment, net	4,677	4,962
Operating lease right of use assets	4,854	4,960
Total assets	$ 56,709	$ 73,665
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,639	$ 6,986
Other	12,870	16,433
Operating lease liabilities	1,000	1,207
Contracts liability	14,793	8,550
Total current liabilities	$ 34,302	$ 33,176
LONG TERM LIABILITIES:		
Convertible notes	$ 28,111	$ 27,887
Contracts liability	-	11,790
Liability for employee rights upon retirement	1,779	2,472
Operating lease liabilities	4,031	4,376
Total long term liabilities	$ 33,921	$ 46,525
Total liabilities	$ 68,223	$ 79,701
COMMITMENTS		
CAPITAL DEFICIENCY	(11,514)	(6,036)
Total liabilities net of capital deficiency	$ 56,709	$ 73,665

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

	Nine Months Ended		Three Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
REVENUES FROM SELLING GOODS	$ 21,222	$ 12,260	$ 8,812	$ 4,506
REVENUES FROM LICENSE AND R&D SERVICES	17,799	17,541	5,371	7,548
TOTAL REVENUE	39,021	29,801	14,183	12,054
COST OF GOODS SOLD (1)	(17,195)	(13,201)	(7,074)	(3,703)
RESEARCH AND DEVELOPMENT EXPENSES (2)	(23,732)	(22,093)	(7,386)	(7,282)

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(8,613)	(9,263)	(2,848)	(2,954)
OPERATING LOSS	(10,519)	(14,756)	(3,125)	(1,885)
FINANCIAL EXPENSES	(1,879)	(6,613)	(639)	(2,410)
FINANCIAL INCOME	1,211	403	197	96
FINANCIAL EXPENSES, NET	(668)	(6,210)	(442)	(2,314)
OTHER INCOME	-	51	-	-
NET LOSS FOR THE PERIOD	$ (11,187)	$ (20,915)	$ (3,567)	$ (4,199)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.24)	$ (0.48)	$ (0.07)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	47,582,733	43,761,769	49,498,105	45,556,647
(1) Includes share-based compensation	$ 58	$ 217	$ 36	$ 65
(2) Includes share-based compensation	$ 275	$ 524	$ 114	$ 154
(3) Includes share-based compensation	$ 1,213	$ 1,216	$ 272	$ 344

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