Protalix BioTherapeutics Reports First Quarter 2022 Financial and Business Results

May 16, 2022

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

CARMIEL, Israel, May 16, 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 first quarter ended March 31, 2022 and provided a business update on recent corporate and clinical developments.

"We are proud of the great progress Protalix has made throughout the first quarter in advancing our Fabry disease candidate PRX-102," said Dror Bashan, Protalix's President and Chief Executive Officer. "The announcement of compelling results from both the BRIGHT and BALANCE phase III trials marks a significant milestone, as we have now completed three phase III studies supporting the planned BLA resubmission to the U.S. Food and Drug Administration later this year. As we work toward potential approval and commercialization, we remain focused on our mission of bringing this important treatment option to patients with Fabry disease, while continuing to advance our early stage pipeline. We are grateful for the unwavering dedication of Chiesi Farmaceutici S.p.A, or Chiesi, our development and commercialization partner, and our other external partners and team members and look forward to building on our momentum throughout the rest of 2022."

2022 First Quarter and Recent Business Highlights

Regulatory Advancements

- As previously announced, on February 24, 2022, the Company, together with Chiesi, announced the submission and subsequent validation of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for PRX-102 for the treatment of adults with Fabry disease. The MAA included final data from the Company's phase III BRIDGE clinical trial (1 mg/kg every other week) and the phase III BRIGHT clinical trial (2 mg/kg every four weeks); 12–month interim data from the Company's phase III BALANCE clinical trial (1 mg/kg every other week); and final data from the Company's phase I/II clinical trial data from naïve/untreated patients, including the extension study related thereto (1 mg/kg every other week).

Clinical Advancements

- On April 4, 2022, the Company, together with Chiesi, announced positive top-line results from its phase III BALANCE clinical trial, a 24-month, randomized, double-blind, active control study designed to evaluate the efficacy and safety of 1 mg/kg of PRX–102 administered every other week compared to agalsidase beta in patients previously treated with agalsidase beta for at least one year. The study met its primary endpoint and demonstrated that PRX-102 was statistically non-inferior to agalsidase beta, as measured by estimated glomerular filtration rate (eGFR) slope. In addition, results showed a favorable tolerability profile for PRX-102, consistent with results from the Company's prior trials.
- On March 18, 2022, the Company, together with Chiesi, announced positive final results from its phase III BRIGHT clinical trial, a multicenter, multinational open-label, switch-over study designed to evaluate the safety, efficacy and pharmacokinetics of treatment with 2 mg/kg of PRX-102 administered every four weeks for 52 weeks (a total of 14 infusions) in adult patients previously treated with a commercially available enzyme replacement therapy (ERT) (Fabrazyme® or Replagal®). Results of the BRIGHT study indicate that 2 mg/kg of PRX–102 administered by intravenous infusion every four weeks was well tolerated, and Fabry disease assessed by eGFR slope and plasma lyso-Gb_3 was stable throughout PRX–102 treatment in adult Fabry patients.

First Quarter 2022 Financial Highlights

- The Company recorded revenues from selling goods of $9.0 million for the three months ended March 31, 2022, an increase of $4.5 million, or 100%, compared to revenues of $4.5 million for the same period of 2021. The increase of $5.4 million in sales to Brazil, resulting from timing differences, was partially offset by a decrease of $1.1 million in sales to Pfizer Inc.
- Revenue from licenses and R&D services for the three months ended March 31, 2022 were $7.1 million, compared to $6.8 million for the same period in 2021. Revenue from license and R&D services are recognized, mainly, in connection with the Company's license and supply agreements with Chiesi.
- Cost of goods sold for the three months ended March 31, 2022 was $6.0 million, an increase of $1.2 million, or 25%, compared to cost of goods sold of $4.8 million for the same period in 2021. The increase in cost of goods sold was primarily the result of higher sales.
- Research and development expenses, for the three months ended March 31, 2022 were $8.8 million, an increase of $1.7 million, or 24%, compared to $7.1 million for the same period in 2021. The increase is primarily the result of subcontractors costs related to the completion of our phase III clinical trials of PRX-102 and maintaining our related extension studies.
- Selling, general and administrative expenses were $3.2 million for the three months ended March 31, 2022, an increase of

$0.1 million, or 3% from $3.1 million for the same period in 2021.

- Financial expenses, net were $0.4 million for the three months ended March 31, 2022, a decrease of $1.4 million, or 78%, compared to $1.8 million for the same period in 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 2021 Notes to an aggregate principal amount of $28.75 million 2024 Notes.
- Cash, cash equivalents and short-term bank deposits were approximately $32.9 million at March 31, 2022.
- Net loss for the three months ended March 31, 2022 was approximately $2.3 million, or $0.05 per share, basic and diluted, compared to a net loss of approximately $5.5 million, or $0.14 per share, basic and diluted, for the same period in 2021.

Conference Call and Webcast Information

The Company will host a conference call today, May 16, 2022, at 8:30 a.m. Eastern Daylight Time, to review the corporate and clinical 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, May 16, 2022, 8:30 a.m. Eastern Daylight Time (EDT)
Domestic: 877-423-9813
International: 201-689-8573
Conference ID: 13729993

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: Registration – https://tinyurl.com/3b4tmnr9
Conference ID: 13729993

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 refractory 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: risks related to the timing and progress of the preparation of a Biologics License Application (BLA) resubmission addressing the complete response letter; risks related to the timing, progress and likelihood of final approval by the FDA and European Medicines Agency (EMA) of a 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; 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; and inability to monitor patients adequately during or after treatment; 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 the novel coronavirus disease, or COVID–19, outbreak, 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; 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; 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; 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, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 16,888	$ 38,985
Short-term bank deposits	16,029	
Accounts receivable – Trade	5,908	3,442
Other assets	1,123	1,285
Inventories	16,594	17,954
Total current assets	$ 56,542	$ 61,666
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 2,052	$ 2,077
Property and equipment, net	4,894	4,962
Operating lease right of use assets	4,903	4,960
Total assets	$ 68,391	$ 73,665
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 7,873	$ 6,986
Other	14,414	16,433
Operating lease liabilities	1,243	1,207
Contracts liability	11,801	8,550
Total current liabilities	$ 35,331	$ 33,176
LONG TERM LIABILITIES:		
Convertible notes	$ 27,962	$ 27,887
Contracts liability	5,895	11,790
Liability for employee rights upon retirement	2,496	2,472
Operating lease liabilities	4,193	4,376
Total long term liabilities	$ 40,546	$ 46,525
Total liabilities	$ 75,877	$ 79,701
COMMITMENTS		
CAPITAL DEFICIENCY	(7,486)	(6,036)
Total liabilities net of capital deficiency	$ 68,391	$ 73,665

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, 2022	March 31, 2021
REVENUES FROM SELLING GOODS	$ 9,028	$ 4,511
REVENUES FROM LICENSE AND R&D SERVICES	7,057	6,809
TOTAL REVENUE	16,085	11,320
COST OF GOODS SOLD (1)	(6,034)	(4,765)

RESEARCH AND DEVELOPMENT EXPENSES (2)	(8,767)	(7,122)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(3,154)	(3,138)
OPERATING LOSS	(1,870)	(3,705)
FINANCIAL EXPENSES	(618)	(2,156)
FINANCIAL INCOME	202	335
FINANCIAL EXPENSES – NET	(416)	(1,821)
OTHER INCOME		51
NET LOSS FOR THE PERIOD	$ (2,286)	$ (5,475)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.05)	$ (0.14)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	45,843,563	39,933,972
(1) Includes share-based compensation	$ (6)	$ 109
(2) Includes share-based compensation	$ 76	$ 210
(3) Includes share-based compensation	$ 766	$ 497

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