Protalix BioTherapeutics Reports Fiscal Year 2021 Financial and Business Results

March 31, 2022

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

CARMIEL, Israel, March 31, 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 fiscal year ended December 31, 2021 and provided a business update on recent corporate and clinical developments.

"2021 was a year of continued progress towards our key operational, clinical and regulatory goals," said Dror Bashan, Protalix's President and Chief Executive Officer. "We had a productive Type A meeting with the FDA in the fall during which the FDA, in principle, agreed that the data package proposed to the FDA for the anticipated BLA resubmission has the potential to support a traditional approval of PRX-102 for the treatment of Fabry disease. We also, together with Chiesi, submitted an MAA to the EMA, which was subsequently validated by the EMA. The submission followed an October 2021 meeting with the EMA's Rapporteur and Co-Rapporteur at which we and Chiesi discussed the scope of the anticipated submission, and the Rapporteur and Co-Rapporteur were generally supportive of a planned MAA submission."

"We are grateful to all of our key stakeholders for their dedication towards our mission of delivering new medicines to patients with high clinical unmet needs. 2022 has the potential to be a meaningful year for the company as we move towards our BLA resubmission in the United States, await feedback on our MAA submission in Europe and continue to advance our early stage pipeline. We look forward to updating you on our progress as the year moves on."

2021 Full-Year and Recent Business Highlights

Regulatory Advancements

- On February 24, 2022, the Company, together with its development and commercialization partner, Chiesi Farmaceutici S.p.A, or Chiesi, announced the submission and subsequent validation of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for PRX-102, the Company's product candidate, for the treatment of adults with Fabry disease. The MAA included final data from the Company's phase III BRIDGE and BRIGHT clinical trials; 12–month interim data from the Company's phase III BALANCE clinical trial; and final data from the Company's phase I/II clinical trial data from naïve/untreated patients, including the extension study related thereto, using 1 mg/kg every other week dosing.
- On October 11, 2021, the Company, together with Chiesi, completed a Type A (End of Review) meeting with the U.S. Food and Drug Administration (FDA) regarding the biologics license application (BLA) for PRX-102 for the treatment of adult patients with Fabry disease, following the complete response letter received on April 27, 2021 from the FDA. The Company gained clarity regarding the FDA's expectations and the FDA, in principle, agreed that the data package proposed to the FDA for the anticipated BLA resubmission has the potential to support a traditional approval of PRX-102 for the treatment of Fabry disease. A BLA resubmission is planned for the second half of 2022.

Clinical Advancements

- On March 18, 2022, the Company, together with Chiesi, announced positive final results from the 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.
- On October 15, 2021, the Company, together with Chiesi, announced the last patient from the phase III BALANCE clinical trial received the final dose in the study. The Company anticipates announcing top-line results from the study next week and final data in the second half of 2022.

- On June 2, 2021, the Company together Chiesi, announced topline results from an interim analysis of the phase III BALANCE clinical trial. The initial top-line results show that the lower boundary of the confidence interval for the mean difference between the two treatments (PRX–102 and Fabrazyme) was below the non-inferiority margin pre-specified for this interim analysis in the ITT analysis set and above such limit in the PP analysis set. At the time of this analysis, two patients had discontinued participation due to treatment emergent adverse events (TEAEs). Of these two patients, one discontinued participation due to a related adverse event. There were no deaths. Overall, safety data appears favorable and consistent with what was observed in previous clinical studies with PRX-102.

Corporate & Financial Developments

- On August 25, 2021, the Company strengthened its balance sheet through exchanges of a substantial majority of its then outstanding 7.50% Senior Secured Convertible Notes due 2021 for a combination of cash and new notes. The Company issued new 7.50% Senior Secured Convertible Notes due 2024 with a $28.75 million aggregate principal amount, and made principal and interest payments of approximately $27.00 million. The remaining 2021 Notes were repaid on the November 2021 maturity date.
- On July 2, 2021, the Company entered into a Sales Agreement with H.C. Wainwright & Co., LLC, as sales agent, or the Agent, pursuant to which the Company may sell from time to time up to $20.0 million worth of shares of its common stock in at-the-market transactions through the Agent. Upon execution of the Sales Agreement, the Company terminated the then existing ATM Equity Offering^{SM} Sales Agreement entered into on October 1, 2020 with BofA Securities.
- On May 13, 2021, the Company and Chiesi entered into a binding term sheet pursuant to which they amended the two exclusive license and supply agreements for PRX-102 in order to provide the Company with near-term capital. Chiesi agreed to make a $10.0 million milestone payment to the Company in exchange for a $25.0 million reduction in a longer-term regulatory milestone payments in the Ex-US Exclusive License and Supply Agreement. All other regulatory and commercial milestone payments remained unchanged. The Company and Chiesi also agreed to negotiate certain manufacturing related matters. The Company received the payment in June 2021.
- On February 17, 2021, the Company successfully completed a public offering of its common stock raising gross proceeds of approximately $40.2 million at a price equal to $4.60 per share, before deducting the underwriting discount and estimated expenses of the offering, which was led by BofA Securities and Oppenheimer & Co.

Financial Results

For the year ended December 31, 2021, compared to the year ended December 31, 2020

- The Company recorded revenues from selling goods of $16.7 million for the year ended December 31, 2021, an increase of $0.5 million, or 3%, compared to revenues of $16.2 million for the same period of 2020.
- Revenue from licenses and R&D services for the year ended December 31, 2021 were $21.6 million, a decrease of $25.1 million, or 54%, compared to $46.7 million for the year ended December 31, 2020. Revenue from license agreements is recognized, mainly, in conjunction with the license and supply agreements with Chiesi. The decrease is primarily due to lower R&D costs related to PRX-102 incurred in the year ended December 31, 2021.
- Cost of goods sold for the year ended December 31, 2021 was $16.3 million, an increase of $5.4 million, or 50%, compared to cost of goods sold of $10.9 million for the same period in 2020. The increase was primarily the result of certain one-time manufacturing costs incurred while preparing for the then anticipated FDA approval of the PRX-102 BLA and higher manufacturing costs.
- Research and development expenses, net, for the year ended December 31, 2021 were $29.7 million, a decrease of $8.5 million, or 22%, compared to $38.2 million for the same period of 2020. The decrease is primarily due to the completion of the three phase III clinical trials of PRX-102.
- Selling, general and administrative expenses were $12.7 million for the year ended December 31, 2021, an increase of $1.6 million, or 14% from $11.1 million for the year ended December 31, 2020. The increase resulted primarily from an increase in corporate costs of $1.7 million related mainly to insurance.
- Financial expenses, net, were $7.1 million for the year ended December 31, 2021, a decrease of $2.1 million, or 23%, compared to financial expenses of $9.2 million for the year ended December 31, 2020. The decrease resulted primary from the exchange of our 2021 notes; a $0.7 million decrease in interest expenses; a $0.8 million decrease in amortization of debt discount; and a $1.3 million decrease in related expenses, offset by a $0.8 million loss on extinguishment related to the Exchanges.
- Cash, cash equivalents and short-term bank deposits were approximately $39.0 million at December 31, 2021.
- Net loss for the year ended December 31, 2021 was approximately $27.6 million, or $0.62 per share, basic and diluted, compared to a net loss of $6.5 million, or $0.22 per share, basic and diluted, for the year ended December 31, 2020.

Conference Call and Webcast Information

The Company will host a conference call today, March 31, 2022, at 8:30 a.m. Eastern Daylight Savings Time, to review the corporate, clinical 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:

Thursday, March 31, 2022, 8:30 a.m. Eastern Daylight Savings Time (EDT)

Domestic: 877-423-9813
International: 201-689-8573
Conference ID: 13727524

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/bdmsa52p

Conference ID: 13727524

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 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.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31,	
	2020	**2021**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 18,265	$ 38,985
Short-term bank deposits	20,280	
Accounts receivable – Trade	2,000	3,442
Other assets	2,096	1,285
Inventories	13,082	17,954
Total current assets	$ 55,723	$ 61,666
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,799	$ 2,077
Property and equipment, net	4,845	4,962
Operating lease right of use assets	5,567	4,960
Total assets	$ 67,934	$ 73,665
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 7,221	$ 6,986
Other	13,926	16,433
Operating lease liabilities	1,420	1,207
Contracts liability	5,394	8,550
Convertible notes	54,427	
Promissory note	4,086	
Total current liabilities	$ 86,474	$ 33,176
LONG TERM LIABILITIES:		
Convertible notes		$ 27,887
Contracts liability	$ 1,716	11,790
Liability for employee rights upon retirement	2,263	2,472
Operating lease liabilities	4,467	4,376
Other long term liabilities	51	
Total long term liabilities	$ 8,497	$ 46,525
Total liabilities	$ 94,971	$ 79,701
COMMITMENTS		
CAPITAL DEFICIENCY		
Common Stock, $0.001 par value: Authorized - as of December 31, 2020 and 2021, 120,000,000 shares; issued and outstanding - as of December 31, 2020 and 2021, 34,765,280 and 45,556,647 shares, respectively	35	46
Additional paid-in capital	320,280	368,852
Accumulated deficit	(347,352)	(374,934)
Total capital deficiency	(27,037)	(6,036)
Total liabilities net of capital deficiency	$ 67,934	$ 73,665

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

	Year Ended December 31,

	2019	2020	2021
REVENUES FROM SELLING GOODS	$ 15,866	$ 16,236	$ 16,749
REVENUES FROM LICENSE AND R&D SERVICES	38,827	46,662	21,601
TOTAL REVENUE	54,693	62,898	38,350
COST OF GOODS SOLD	(10,895)	(10,873)	(16,349)
RESEARCH AND DEVELOPMENT EXPENSES, NET	(44,616)	(38,167)	(29,734)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(9,899)	(11,148)	(12,729)
OPERATING INCOME (LOSS)	(10,717)	2,710	(20,462)
FINANCIAL EXPENSES	(7,966)	(9,671)	(7,521)
FINANCIAL INCOME	407	438	401
FINANCIAL EXPENSES – NET	(7,559)	(9,233)	(7,120)
NET LOSS FOR THE YEAR	$ (18,276)	$ (6,523)	$ (27,582)
LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (1.23)	$ (0.22)	$ (0.62)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	14,838,213	29,148,047	44,140,233

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