Protalix BioTherapeutics Reports Fiscal Year 2020 Financial and Business Results

March 30, 2021

In February 2021, announced positive top-line results from the Company's phase III BRIGHT clinical trial
In December 2020, announced positive final results from the Company's phase III BRIDGE clinical trial
Successfully raised approximately $40 million in gross proceeds in an equity offering led by BofA Securities and Oppenheimer
Management to host conference call and live webcast today at 8:30 am EDT

CARMIEL, Israel, March 30, 2021 /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, 2020 and provided a business update on recent corporate and clinical developments.

"2020 was an important year for Protalix, as we continued to strengthen the clinical profile of PRX–102 for the treatment of Fabry disease and advance towards potential commercialization of our lead pipeline program," said Dror Bashan, Protalix's President and Chief Executive Officer. "We advanced our earlier stage pipeline with the exclusive partnership we announced with SarcoMed USA for our PRX–110 asset, and we solidified our balance sheet to provide the financial backing to drive the Company through our 2021 milestones."

"We expect 2021 will also be an important year for Protalix as we await the FDA's review of the PRX–102 BLA on the upcoming April 27, 2021 PDUFA date. We are grateful to our employees and external partners for their commitment and dedication during a very challenging time with the global pandemic. We look forward to continuing to build stockholder value," concluded Mr. Bashan.

2020 Full-Year and Recent Business Highlights

Regulatory Advancements

- On August 11, 2020, the Company, together with its development and commercialization partner, Chiesi Farmaceutici S.p.A., or Chiesi, announced that the FDA had accepted the BLA for PRX–102, and granted Priority Review designation for PRX–102, for the proposed treatment of adult patients with Fabry disease. The FDA indicated in the BLA filing communication letter that it is not currently planning to hold an advisory committee meeting to discuss the application. The FDA set a PDUFA action date of January 27, 2021. However, as previously announced in November 2020, the FDA subsequently extended the PDUFA action date to April 27, 2021. As we disclosed last year, the FDA has advised that it will have to inspect our manufacturing facility and the facility of a third party in Europe that performs fill and finish processes for PRX-102 as part of its review of the BLA to ensure cGMP compliance. Due to COVID-19-related FDA travel restrictions, the FDA has advised that it may be unable to conduct the inspections prior to the PDUFA action date. The Company, together with Chiesi, is addressing this issue.

Clinical Advancements

- On February 23, 2021, the Company, together Chiesi, announced positive topline results from the phase III BRIGHT clinical trial, a study designed to evaluate the safety, efficacy and pharmacokinetics of pegunigalsidase alfa, or PRX–102, treatment, 2 mg/kg every four weeks, in up to 30 patients with Fabry disease previously treated with a commercially available enzyme replacement therapy (ERT) (agalsidase alfa – Replagal® or agalsidase beta – Fabrazyme®). Topline results indicate that 2 mg/kg of PRX-102 administered by intravenous infusion every four weeks was found to be well tolerated among treated patients, and stable clinical presentation was maintained in adult Fabry patients.
- On December 30, 2020, the Company, together with Chiesi, announced final study results from the phase III BRIDGE clinical trial, a 12–month open-label, single arm switch-over study evaluating the safety and efficacy of PRX–102, 1 mg/kg infused every two weeks, in up to 22 Fabry patients. Final results of the data generated in the study showed substantial improvement in renal function as measured by mean annualized estimated Glomerular Filtration Rate (eGFR slope) in both male and female patients who were switched from agalsidase alfa to PRX-102.
- On October 2, 2020, the Company, together with Chiesi, announced the launch of an Expanded Access Program (EAP) in the United States for PRX–102 for the proposed treatment of Fabry disease.

Corporate & Financial Developments

- 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.
- On February 10, 2021, the Company entered into an exclusive partnership with SarcoMed USA for the worldwide development and commercialization of alidornase alfa, or PRX-110, for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis and other related diseases via inhaled delivery.

- On March 18, 2020, the Company successfully completed a private placement of its common stock to certain existing and new institutional and other accredited investors raising aggregate net proceeds of approximately $41.3 million at a price equal to $2.485 per share. Each share of common stock issued in the transaction was accompanied by a warrant to purchase an additional share of common stock at an exercise price equal to $2.36.
- On March 16, 2020, the Company announced that it had agreed to conduct a feasibility study with Kirin Holdings Company, Limited, or Kirin, to evaluate the production of a novel complex protein utilizing ProCellEx. Kirin is providing research funding for Protalix scientists to conduct cell line engineering and protein expression studies on the target protein.

Financial Results

For the year ended December 31, 2020, compared to the year ended December 31, 2019

- The Company recorded revenues from selling goods of $16.2 million for the year ended December 31, 2020 compared to revenues of $15.9 million for the same period of 2019.
- Revenue from licenses and R&D services for the year ended December 31, 2020 were $46.7 million compared to $38.8 million for the year ended December 31, 2019. Revenue from license agreements is recognized in conjunction with the license and supply agreements with Chiesi. The increase is primarily due to revenues recognized in connection with an updated cost estimation of two completed phase III clinical trials of PRX-102.
- Cost of goods sold was $10.9 million for the years ended December 31, 2020, and December 31, 2019.
- Research and development expenses net for the year ended December 31, 2020 were $38.2 million compared to $44.6 million for the year ended December 31, 2019. The decrease is primarily due to the completion of two out of the three phase III clinical trials of PRX-102 and reduced costs related to the phase III BALANCE study, as well as a decrease in costs related to manufacturing of the Company's drug in development as some of the manufactured drug product and related costs have been recorded as inventory. The Company expects research and development expenses to continue to be its primary expense as it enters into a more advanced stage of preclinical and clinical trials for certain of its product candidates.
- Selling, general and administrative expenses were $11.1 million for the year ended December 31, 2020, an increase of $1.2 million, or 12%, from $9.9 million for the year ended December 31, 2019. The increase resulted primarily from an increase in share-based compensation costs.
- Financial expenses, net was $9.2 million for the year ended December 31, 2020 compared to $7.6 million for the same period of 2019.
- Cash, cash equivalents and short-term bank deposits were approximately $38.5 million on December 31, 2020. During the first quarter of 2021, the Company raised gross proceeds of $8.8 million from the sale of common stock under its ATM program and gross proceeds of $40.2 million via the public offering of its common stock.
- Net loss for the year ended December 31, 2020 was $6.5 million, or $0.22 per share, basic and diluted, compared to a net loss of $18.3 million, or $1.23 per share, basic and diluted, for the same period in 2019.

Conference Call and Webcast Information

The Company will host a conference call today, March 30, 2021 at 8:30 am Eastern Daylight Time, to review the clinical, corporate, and financial highlights, 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:

Tuesday, March 30, 2021, 8:30 a.m. Eastern Daylight Time (EDT)
Domestic: 1-877-413-2408
International: 201-689-8573
Conference ID: 13716316

The conference call will be webcast live from the Company's website and will be available via the following links:

Webcast Details:

Company Link: https://protalixbiotherapeutics.gcs-web.com/events0
Webcast Link: https://tinyurl.com/hz84rysc
Conference ID: 13716316

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 for marketing 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 version of the recombinant human α-Galactosidase-A protein for the

proposed 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, and with SarcoMed USA, Inc. for the worldwide development and commercialization of PRX-110 for use in the treatment of any human respiratory disease or condition including, but not limited to, sarcoidosis, pulmonary fibrosis, and other related diseases via inhaled delivery.

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: failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: the timing, progress and likelihood of approval by the U.S. Food and Drug Administration of the Biologics License Application for PRX-102 by the PDUFA date or at all, and, if approved, whether the use of PRX-102 will be commercially successful; the risk that the FDA, the European Medicines Agency or other foreign regulatory authorities may not accept or approve a marketing application we file for any of our product candidates; risks associated with the novel coronavirus disease, or COVID-19, outbreak, which may adversely impact our business, preclinical studies and clinical trials; 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; 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; delays in the approval or potential rejection of any applications we file with the FDA or other health regulatory authorities, and other risks relating to the review process; 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,	
	2019	**2020**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 17,792	$ 18,265
Short-term bank deposits	-	20,280
Accounts receivable – Trade	4,700	2,000
Other assets	1,832	2,096
Inventories	8,155	13,082
Total current assets	$ 32,479	$ 55,723
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,963	$ 1,799
Property and equipment, net	5,273	4,845
Operating lease right of use assets	5,677	5,567
Total assets	$ 45,392	$ 67,934
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,495	$ 7,221

Other	11,905	13,926
Operating lease liabilities	1,139	1,420
Contracts liability	16,335	5,394
Convertible notes	-	54,427
Promissory note	4,301	4,086
Total current liabilities	$ 40,175	$ 86,474
LONG TERM LIABILITIES:		
Convertible notes	$ 50,957	-
Contracts liability	16,980	$ 1,716
Liability for employee rights upon retirement	2,565	2,263
Operating lease liabilities	4,528	4,467
Other long term liabilities	509	51
Total long term liabilities	$ 75,539	$ 8,497
Total liabilities	$ 115,714	$ 94,971
COMMITMENTS		
CAPITAL DEFICIENCY		
Common Stock, $0.001 par value: Authorized - as of December 31, 2019 and 2020, 120,000,000 shares; issued and outstanding - as of December 31, 2019 and 2020, 14,838,213 and 34,765,280 shares, respectively	15	35
Additional paid-in capital	270,492	320,280
Accumulated deficit	(340,829)	(347,352)
Total capital deficiency	(70,322)	(27,037)
Total liabilities net of capital deficiency	$ 45,392	$ 67,934

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

	Year Ended December 31,		
	2018	**2019**	**2020**
REVENUES FROM SELLING GOODS	$ 8,978	$ 15,866	$ 16,236
REVENUES FROM LICENSE AND R&D SERVICES	25,262	38,827	46,662
TOTAL REVENUE	34,240	54,693	62,898
COST OF GOODS SOLD	(9,302)	(10,895)	(10,873)
RESEARCH AND DEVELOPMENT EXPENSES, NET (1)	(33,330)	(44,616)	(38,167)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(10,916)	(9,899)	(11,148)
OPERATING INCOME (LOSS)	(19,308)	(10,717)	2,710
FINANCIAL EXPENSES	(7,685)	(7,966)	(9,671)
FINANCIAL INCOME	536	407	438
FINANCIAL EXPENSES - NET	(7,149)	(7,559)	(9,233)
NET LOSS FOR THE YEAR	$ (26,457)	$ (18,276)	$ (6,523)
NET LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED	$ (1.80)	$ (1.23)	$ (0.22)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	14,713,518	14,838,213	29,148,047
(1) Includes deductible grants	$ 2,204	$ 77	$ 75

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