Protalix BioTherapeutics Reports First Quarter 2021 Financial Results and Business Update

May 14, 2021

Management to host conference call and live webcast today at 8:30 am EDT

CARMIEL, Israel, May 14, 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 first quarter ended March 31, 2021 and provided a business update.

"While the receipt of the Complete Response Letter last month from the FDA was disappointing, we are encouraged that the FDA did not report any potential safety or efficacy concerns for PRX-102," said Dror Bashan, Protalix's President and Chief Executive Officer. "We are working closely with the FDA and anticipate the required inspection and subsequent assessment will be completed once the FDA's travel restrictions are lifted. We continue to advance our earlier stage pipeline and anticipate continued progress throughout 2021. We are grateful for the support of our clinicians, patients, shareholders, Board members, employees and external partners and look forward to building stockholder value," concluded Mr. Bashan.

2021 First Quarter and Recent Business Update

Regulatory Updates

- On April 28, 2021, the Company, together with its development and commercialization partner, Chiesi Farmaceutici S.p.A., or Chiesi, announced the receipt of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the Biologics License Application (BLA) seeking accelerated approval of pegunigalsidase alfa, or PRX–102, for the proposed treatment of adult patients with Fabry disease. The CRL did not report any concerns relating to the potential safety or efficacy of PRX-102 in the submitted data package. In the CRL the FDA noted an inspection of the Company's manufacturing facility in Carmiel, Israel, including the FDA's subsequent assessment of any related findings is required before the FDA can approve the BLA. Due to travel restrictions relating to the COVID-19 pandemic, the FDA was unable to conduct the required inspection during the review cycle. The FDA explained that it will continue to monitor the public health situation as well as travel restrictions, and is actively working to schedule outstanding inspections.

Clinical Advancements

- On February 23, 2021, the Company, together with Chiesi, announced positive topline results from the phase III BRIGHT clinical trial, a study designed to evaluate the safety, efficacy and pharmacokinetics of 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.

Corporate & Financial Developments

- Given the receipt of the CRL, the Company believes that it is prudent to secure short-term funds in order to continue development of PRX-102 while waiting for the FDA's required inspection and subsequent assessment described in the CRL. To do so, 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 before the end of the second quarter in exchange for a $25.0 million reduction in a longer-term regulatory milestone payment in the Ex-US Exclusive License and Supply Agreement. All other regulatory and commercial milestone payments remain unchanged. The Company and Chiesi also agreed to negotiate certain manufacturing related matters.
- On February 18, 2021, the Company announced the closing of a public offering of common stock raising gross proceeds of approximately $40.2 million before deducting the underwriting discount and estimated expenses of the offering.
- On February 10, 2021, the Company entered into an exclusive partnership with SarcoMed USA Inc. 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.

Financial Results

For the three months ended March 31, 2021, compared to the three months ended March 31, 2020

- The Company recorded revenues from selling goods of $4.5 million during the three months ended March 31, 2021, a decrease of $0.5 million, or 10%, compared to revenues of $5.0 million for the same period of 2020. The decrease of $3.0 million in sales to Brazil was partially offset by an increase of $2.5 million in sales to Pfizer Inc. or Pfizer.
- Revenue from licenses and R&D services was $6.8 million for the three months ended March 31, 2021, a decrease of $9.8 million, or 59%, compared to revenues from license and R&D services of $16.6 million for the same period in 2020. Revenues from license and R&D services are comprised primarily of revenues we recognized in connection with the

license and supply agreements with Chiesi. The decrease resulted primarily from revenues for the three months ended March 31, 2020 recognized in connection with an updated costs estimation throughout the trials until completion, made in 2020, in the amount of $6.7 million and from revenues recognized in connection with the progress of our clinical trials that have been completed during 2020.

- Cost of goods sold was $4.8 million for the three months ended March 31, 2021, an increase of $1.4 million, or 41%, from cost of goods sold of $3.4 million for the same period in 2020. The increase in cost of goods sold was primarily the result of higher manufacturing costs.
- Research and development expenses were $7.1 million for the three months ended March 31, 2021, a decrease of $3.2 million, or 31%, compared to $10.3 million of research and development expenses for the same period of 2020. 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 *BALANCE* Study. 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 $3.1 million for the three months ended March 31, 2021, a decrease of $0.1 million, or 3%, compared to $3.2 million for the same period of 2020.
- Financial expenses, net were $1.8 million for the three months ended March 31, 2021, a decrease of $1.2 million, or 40%, compared to financial expenses net of $3.0 million for the same period of 2020. The decrease resulted primarily from a decrease in expenses related to the Company's outstanding convertible notes equal to $1.3 million.
- Cash, cash equivalents and short-term bank deposits were approximately $70.4 million on March 31, 2021. 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 three months ended March 31, 2021 was approximately $5.5 million, or $0.14 per share, basic and diluted, compared to a net income of $1.7 million, or $0.10 per share, basic and diluted, for the same period in 2020.

Conference Call and Webcast Information
The Company will host a conference call today, May 14, 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:
Friday, May 14, 2021, 8:30 a.m. Eastern Daylight Time (EDT)
Domestic: 877-423-9813
International: 201-689-8573
Conference ID: 13719725

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/bnd6y9ch
Conference ID: 13719725

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 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, 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: risks related to the timing and progress of the preparation of an updated BLA addressing the complete response letter; risks related to the timing, progress and likelihood of final approval by the FDA of a resubmitted BLA for PRX–102 and, if approved, whether the use of PRX-102 will be commercially successful; the risk that the FDA, the European Medicines Agency, or EMA, or other foreign regulatory authorities may not accept or approve a marketing application the Company files for any of its 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 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 relating to the Company's ability to make required payments under its outstanding convertible notes or any other indebtedness as they come due and the Company's ability to obtain additional financing and raise capital as necessary should the regulatory approval process become more extended; 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; risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector; 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; 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, EMA 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	March 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 19,830	$ 18,265
Short-term bank deposits	50,600	20,280
Accounts receivable – Trade	4,599	2,000
Other assets	1,754	2,096
Inventories	13,915	13,082
Total current assets	$ 90,698	$ 55,723
NON-CURRENT ASSETS:		
Funds in respect of employee rights upon retirement	$ 1,776	$ 1,799
Property and equipment, net	4,828	4,845
Operating lease right of use assets	5,490	5,567
Total assets	$ 102,792	$ 67,934
LIABILITIES AND STOCKHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,376	$ 7,221
Other	15,167	13,926
Operating lease liabilities	1,386	1,420
Contracts liability	2,560	5,394
Convertible notes	55,372	54,427
Promissory note		4,086
Total current liabilities	$ 80,861	$ 86,474
LONG TERM LIABILITIES:		
Contracts liability	858	1,716
Liability for employee rights upon retirement	2,224	2,263
Operating lease liabilities	4,319	4,467
Other long term liabilities	26	51
Total long term liabilities	$ 7,427	$ 8,497
Total liabilities	$ 88,288	$ 94,971
STOCKHOLDERS' EQUITY (CAPITAL DEFICIENCY)	14,504	(27,037)

Total liabilities and stockholders' equity (net of capital deficiency)	$ 102,792	$ 67,934

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, 2021	**March 31, 2020**
REVENUES FROM SELLING GOODS	$ 4,511	$ 5,031
REVENUES FROM LICENSE AND R&D SERVICES	6,809	16,615
TOTAL REVENUE	11,320	21,646
COST OF GOODS SOLD (1)	(4,765)	(3,426)
RESEARCH AND DEVELOPMENT EXPENSES, NET (2)	(7,122)	(10,340)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (3)	(3,138)	(3,187)
OPERATING INCOME (LOSS)	(3,705)	4,693
FINANCIAL EXPENSES	(2,156)	(3,229)
FINANCIAL INCOME	335	203
FINANCIAL EXPENSES – NET	(1,821)	(3,026)
OTHER INCOME	51	
NET INCOME (LOSS) FOR THE PERIOD	$ (5,475)	$ 1,667
EARNINGS (LOSS) PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.14)	$ 0.10
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE – BASIC AND DILUTED	39,933,972	17,381,074
(1) Includes share-based compensation	$ 109	$
(2) Includes share-based compensation	$ 210	$ 78
(3) Includes share-based compensation	$ 497	$ 353

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