Protalix BioTherapeutics Reports First Quarter 2020 Financial Results and Business Update

June 1, 2020

Conference call and live webcast scheduled for Monday, June 1st, 2020 at 8:30 am EDT

CARMIEL, Israel, June 1, 2020 /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, 2020, and provided a business update on recent corporate and clinical developments. The Company's management will discuss the financial results and provide a clinical, corporate and financial highlights on a conference call and live webcast scheduled for Monday, June 1, 2020 at 8:30 am Eastern Daylight Time (EDT).

"The first quarter of 2020 has most certainly been transformational for Protalix, despite the COVID-19 pandemic that affected the global markets," said Dror Bashan, Protalix's President and Chief Executive Officer. "I am proud to say that despite the pandemic, Protalix was able to keep the company running smoothly and adapt quickly to the changing environment."

"During the quarter, we were able to close a $43.7 million private placement," he continued. "Furthermore, the topline results from the completion of our Phase III BRIDGE study and the subsequent BLA submission for PRX–102 announced in May prove that Protalix has actually gained momentum by leaning into this unprecedented challenge. I am convinced now more than ever that our team is positioned for long-term success and look forward to continuing our momentum through the rest of this year and into 2021."

Conference Call and Webcast Information

The Company will host a conference call on Monday, June 1, 2020, at 8:30 am, Eastern Daylight Time, to review the clinical, corporate and financial highlights. To participate in the conference call, please dial the following numbers prior to the start of the call:

Domestic: 877-423-9813
International: 201-689-8573
Conference ID: 13704328
Webcast: https://tinyurl.com/yc32s9jn

The conference call will also be broadcast live and available for replay for two weeks on the Company's website, www.protalix.com, in the Events Calendar of the Investors section. Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software.

First Quarter 2020 and Recent Business Highlights

Clinical and Regulatory Advancements

- On May 28, 2020, the Company and its development and collaboration partner, Chiesi Global Rare Diseases, a unit of Chiesi Farmaceutici S.p.A., or Chiesi, announced the submission on May 27, 2020 of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for pegunigalsidase alfa, or PRX–102, for the treatment of adult patients with Fabry disease via the FDA's Accelerated Approval pathway. PRX–102 was granted Fast Track designation by the FDA in January 2018. Upon the BLA approval, if approved, the Company will be eligible to receive a milestone payment from Chiesi.
- On May 11, 2020, the Company announced positive topline results following the completion of its Phase III BRIDGE clinical trial of PRX–102 for the treatment of Fabry disease. 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, met its main objectives for safety and efficacy, and topline analysis indicated substantial improvement in renal function as measured by mean annualized estimated Glomerular Filtration Rate (eGFR slope) in patients switched from agalsidase alfa to PRX–102.
- On February 6, 2020, Protalix and Chiesi announced the receipt of an agreement letter from the FDA for the Initial Pediatric Study Plan (iPSP) for PRX-102 for the treatment of Fabry disease, outlining an agreed-upon approach to address the needs of pediatric Fabry patients.

Corporate & Financial Developments

- On March 16, 2020, the Company announced that it has agreed to conduct a feasibility study with Kirin Holdings Company, Limited, or Kirin, to evaluate the production of a novel complex protein utilizing ProCellEx. The Company received a non-refundable payment of $1.0 million and Kirin will provide research funding for the Company's scientists to conduct cell line engineering and protein expression studies on the target protein.
- On March 12, 2020, the Company entered into securities purchase agreements with certain existing and new institutional and other accredited investors in a private placement. Pursuant to such agreements, the Company issued and sold to the purchasers an aggregate of approximately 17.6 million unregistered shares of its common stock at a price per share of $2.485, or aggregate net committed proceeds equal to approximately $41.3 million. Each share of the Company's 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.

Financial Results

For the three months ended March 31, 2020, compared to the three months ended March 31, 2019

- The Company recorded revenues from selling goods of $5.0 million during the three months ended March 31, 2020, an increase of $1.5 million, or 43%, compared to revenues of $3.5 million for the same period of 2019. The increase resulted primarily from an increase of $0.8 million in sales of drug product to Brazil as well as an increase of $0.7 million in sales of drug substance to Pfizer Inc.
- Revenues from license and R&D services for the three months ended March 31, 2020, were $16.6 million, an increase of $9.7 million, or 140%, compared to revenues of $6.9 million for the same period of 2019. Revenues from the license agreements represent the revenues recognized in connection with previously announced agreements with Chiesi. The increase is primarily due to revenues recognized in connection with the progress of the Company's clinical trial that have been performed, and with revenues recognized in connection with an updated costs estimation throughout the trials until completion in the amount of $6.7 million.
- Cost of goods sold was $3.4 million for the three months ended March 31, 2020, an increase of $1.4 million, or 68%, from cost of goods sold of $2.0 million for the same period of 2019. The increase is primarily due to an increase in sales of goods.
- Research and development expenses were $10.3 million for the three months ended March 31, 2020, a decrease of $1.4 million, or 12%, compared to $11.7 million of research and development expenses for the same period of 2019. The decrease was primarily due to a decrease in costs related to manufacturing of our drug in development.
- Selling, general and administrative expenses were $3.2 million for the three months ended March 31, 2020, an increase of $1.0 million, or 43%, compared to $2.2 million for the same period of 2019. The increase resulted primarily from a $0.6 million increase in compensation related costs and a $0.2 million increase in professional fees.
- Net income for the three months ended March 31, 2020 was $1.7 million, or $0.10 per share, basic and diluted, compared to a net loss of $7.3 million, or $0.50 per share, basic and diluted, for the same period of 2019.

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; OPRX–106, an orally-delivered anti-inflammatory treatment; alidornase alfa for the treatment of Cystic Fibrosis; 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," "plan," "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 that the FDA will not accept an application for accelerated approval of PRX–102 with the data generated to date or will request additional data or other conditions of our submission of any application for accelerated approval of PRX–102 and, if approved, whether PRX–102 will be commercially successful; failure or delay in the commencement or completion of our preclinical 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 monitor patients adequately during or after treatment; and inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; risks associated with the novel coronavirus disease (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 our claims of safety or efficacy, 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 Chiesi Farmaceutici and any other collaborator, distributor or partner; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the ultimate purchase by Fundação Oswaldo Cruz of BioManguinhos alfataliglicerase pursuant to the stated purchase intentions of the Brazilian Ministry of Health of the stated amounts, if at all; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of BioManguinhos alfataliglicerase generally; risks related to our commercialization efforts for BioManguinhos alfataliglicerase in Brazil; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; risks related to the amount and sufficiency of our cash and cash equivalents; the risk that despite the FDA's grant of fast track designation for PRX–102, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA's ability to withdraw the fast track designation at any time; 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; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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.

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

	March 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 14,166	$ 17,792
Short-term bank deposits	22,509	-
Accounts receivable – Trade	8,876	4,700
Other assets	2,728	1,832
Inventories	9,488	8,155
Total current assets	$ 57,767	$ 32,479
NON-CURRENT ASSETS:		
Long-term bank deposits	$ 12,505	-
Funds in respect of employee rights upon retirement	1,879	$ 1,963
Property and equipment, net	5,012	5,273
Operating lease right of use assets	5,713	5,677
Total non-current assets	$ 25,109	$ 12,913
Total assets	$ 82,876	$ 45,392
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 9,430	$ 6,495
Other	13,757	11,905
Operating lease liabilities	1,126	1,139
Contracts liability	19,014	16,335
Promissory Note	4,301	4,301
Total current liabilities	$ 47,628	$ 40,175
LONG TERM LIABILITIES:		
Convertible notes	$ 51,777	$ 50,957
Contracts liability	7,130	16,980
Liability for employee rights upon retirement	2,531	2,565

Operating lease liabilities	4,481	4,528
Other long term liabilities	210	509
Total long term liabilities	$ 66,129	$ 75,539
Total liabilities	$ 113,757	$ 115,714
COMMITMENTS		
CAPITAL DEFICIENCY	(30,881)	(70,322)
Total liabilities net of capital deficiency	$ 82,876	$ 45,392

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

	Three Months Ended	
	March 31, 2020	March 31, 2019
REVENUES FROM SELLING GOODS	$ 5,031	$ 3,530
REVENUES FROM LICENSE AND R&D SERVICES	16,615	6,909
TOTAL REVENUE	21,646	10,439
COST OF GOODS SOLD	(3,426)	(2,045)
RESEARCH AND DEVELOPMENT EXPENSES, NET (1)	(10,340)	(11,698)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(3,187)	(2,230)
OPERATING INCOME (LOSS)	4,693	(5,534)
FINANCIAL EXPENSES	(3,229)	(1,920)
FINANCIAL INCOME	203	190
FINANCIAL EXPENSES, NET	(3,026)	(1,730)
NET INCOME (LOSS) FOR THE PERIOD	$ 1,667	$ (7,264)
EARNINGS (LOSS) PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ 0.10	(0.50)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING EARNINGS (LOSS) PER SHARE-BASIC AND DILUTED	17,381,074	14,838,213
(1) Includes share-based compensation	$ 78	$ 178
(2) Includes share-based compensation	$ 353	$ 112

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