Protalix BioTherapeutics Reports Second Quarter 2019 Results and Provides Corporate Update

August 8, 2019

CARMIEL, Israel, Aug. 08, 2019 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®, today announced its financial results for the six-month period ended June 30, 2019 and provided a corporate update.

"We are very optimistic about our interactions with the U.S. Food and Drug Administration over the second quarter of 2019, which resulted in our decision to, together with our partner Chiesi Farmaceutici, begin preparing a biologics license application for pegunigalsidase alfa for the treatment of Fabry disease, which we expect to submit in the first quarter of 2020 through the FDA's Accelerated Approval pathway," said Mr. Dror Bashan, Protalix's President and Chief Executive Officer. "We are now focused on completing the anticipated filing."

Second Quarter 2019 and Recent Clinical and Corporate Highlights

- The Company, together with its collaboration partner, Chiesi Farmaceutici S.p.A, or Chiesi, announced that, following a series of meetings and correspondence with the U.S. Food and Drug Administration (FDA), they plan to file a biologics license application (BLA) for pegunigalsidase alfa, or PRX-102, for the treatment of Fabry disease via the FDA's Accelerated Approval pathway.

- The Company and Chiesi have initiated preparations for the BLA submission based on data from the completed Phase I/II clinical trials of pegunigalsidase alfa and the ongoing Phase III BRIDGE clinical trial, and expect to hold a pre-BLA meeting with the FDA in the fourth quarter of 2019.

- Enrollment completed in the Phase III BRIGHT clinical trial of pegunigalsidase alfa for the treatment of Fabry disease, via intravenous (IV) infusions of 2 mg/kg administered every 4 weeks.

- To date, substantially all patients enrolled in the BRIGHT clinical trial remain on the 4-week dosing regimen, and all of the patients that completed the study opted, with the advice of the treating physician, to continue treatment under the 4-week dosing regimen in a long-term extension study.

- The Company's Phase III BALANCE clinical trial of pegunigalsidase alfa for the treatment of Fabry disease is currently 95% enrolled.

- To date, more than 55 patients are being treated in the Company's various extension studies after opting to continue treatment with pegunigalsidase alfa after completion of an initial study.

- Results from the Company's Phase I/II clinical trial of pegunigalsidase alfa were published in an article in the May 2019 edition of the *Journal of Inherited Metabolic Disease*.

Financial Results for the Six Months Ended June 30, 2019

- The Company recorded total revenues of $22.7 million for the six-month period ended June 30, 2019, compared to $11.6 million for the same period of 2018. The increase is primary attributable to the recognition of $15.7 million of license revenues for the six-month period ended June 30, 2019 compared to the recognition of $5.0 million in the same period of 2018.

- Research and development expenses, net were $25.0 million for the six months ended June 30, 2019, compared to $13.7 million for the same period in 2018. The increase is mainly due to advancement of the Phase III studies in PRX-102.

- Selling, general and administrative expenses for the six months ended June 30, 2019 were $4.3 million, compared to $4.7 million for the same period in 2018.

- Net loss for the six months ended June 30, 2019 was $15.0 million, or $0.10 per share, basic and diluted, compared to a net loss of $15.7 million, or $0.11 per share, basic and diluted, for the six months ended June 30, 2018.

- On June 30, 2019, the Company had $25.1 million of cash and cash equivalents.

- If the BLA submitted for pegunigalsidase alfa is approved by the FDA, the Company will be entitled to a milestone payment, which is currently expected to be payable around the fourth quarter of 2020 or first quarter of 2021.

- Based on the Company's current cash resources and commitments, the Company believes it may not be able to maintain its current planned development activities and the corresponding level of expenditures for at least 12 months from the date of approval of the financial statements as of June 30, 2019 in the absence of a refinancing or restructuring of its existing obligations. These factors raise substantial doubt as to the Company's ability to continue as a going concern. Additional information will be included in Note 1(a) and other parts of the Company's Quarterly Report on Form 10-Q which will be filed the day of the earnings call. The Company is evaluating various financing alternatives and related transactions.

- The Company's management is in the process of evaluating refinancing and restructuring alternatives, including a restructuring of its outstanding convertible notes, and related transactions. However, there is no certainty about the Company's ability to obtain such funding.

Conference Call and Webcast Information

The Company will host a conference call on Thursday, August 8, 2019, at 8:30 am ET 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: United States: +1 (844) 358-6760; International: +1 (478) 219-0004. Conference ID number 1497319.

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.

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's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (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 includes the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human alpha-GAL-A protein for the 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: failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: 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; risks related to our ability to continue as a going concern absent access to sources of capital we will need to finance future research and development activities, general and administrative expenses and working capital; risks related to any capital raising 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; 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; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of our product candidates will not support our claims of superiority, 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 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 alfataliglicerase generally; risks related to our commercialization efforts for 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; risks related to the amount of our future revenues, operations and expenditures; the risk that despite the FDA's grant of fast track designation for pegunigalsidase alfa for the treatment of Fabry disease, 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.

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

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 25,096	$ 37,808
Accounts receivable – Trade	7,256	4,729
Other assets	2,248	1,877
Inventories	6,998	8,569
Total current assets	$ 41,598	$ 52,983
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	$ 1,871	$ 1,758
PROPERTY AND EQUIPMENT, NET	5,917	6,390
OPERATING LEASE RIGHT OF USE ASSETS	5,856	**-**
Total assets	$ 55,242	$ 61,131
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,728	$ 5,211
Other	10,496	10,274
Operating lease liabilities	1,227	-
Contracts liability	7,542	9,868
Total current liabilities	$ 25,993	$ 25,353
LONG TERM LIABILITIES:		
Convertible notes	$ 49,401	$ 47,966
Contracts liability	34,911	33,027
Liability for employee rights upon retirement	2,508	2,374
Operating lease liabilities	4,566	-
Other long term liabilities	5,348	5,292
Total long term liabilities	$ 96,734	$ 88,659
Total liabilities	$ 122,727	$ 114,012
COMMITMENTS		
CAPITAL DEFICIENCY	$ (67,485)	$ (52,881)
Total liabilities net of capital deficiency	$ 55,242	$ 61,131

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

	Six Months Ended		Three Months Ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
REVENUES FROM SELLING GOODS	$ 6,960	$ 6,559	$ 3,430	$ 2,006
REVENUES FROM LICENSE AND R&D SERVICES	15,726	4,993	8,817	2,832
COST OF GOODS SOLD	(4,740)	(5,107)	(2,695)	(2,183)
RESEARCH AND DEVELOPMENT EXPENSES (1)	(25,024)	(14,762)	(13,323)	(7,476)
Less - grants	3	1,078		235
RESEARCH AND DEVELOPMENT EXPENSES, NET	(25,021)	(13,684)	(13,323)	(7,241)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(4,298)	(4,656)	(2,068)	(2,158)
OPERATING LOSS	(11,373)	(11,895)	(5,839)	(6,744)
FINANCIAL EXPENSES	(3,827)	(4,013)	(1,907)	(1,793)
FINANCIAL INCOME	193	207	3	75
FINANCIAL EXPENSES, NET	(3,634)	(3,806)	(1,904)	(1,718)
NET LOSS FOR THE PERIOD	$ (15,007)	$ (15,701)	$ (7,743)	$ (8,462)
NET LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED	$ (0.10)	$ (0.11)	$ (0.05)	$ (0.06)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	148,382,299	145,985,445	148,382,299	146,644,450
(1) Includes share-based compensation	$ 316	$ 40	$ 138	$ (2)
(2) Includes share-based compensation	$ 87	$ 34	$ (25)	$ 14

Source: Protalix BioTherapeutics, Inc.