Protalix BioTherapeutics Reports 2018 Full Year Results and Provides Corporate Update

March 18, 2019

CARMIEL, Israel, March 18, 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 full-year ended December 31, 2018 and provided a corporate update.

"Throughout 2018 and into early 2019, we significantly advanced our clinical development program for PRX-102 and, as of today, have enrolled 127 Fabry disease patients across all of our PRX-102 clinical trials. Most recently, we had a very productive meeting with the U.S. Food and Drug Administration (FDA) to discuss the potential filing of an application for accelerated approval and, at the FDA's request, we intend to hold a follow up meeting by the end of the second quarter of 2019 to discuss the data and content of the potential filing for accelerated approval. We are very pleased with the collaborative manner our engagement with the FDA has been to date and cautiously optimistic about the prospects of our discussions with the agency," said Mr. Moshe Manor, Protalix's President and Chief Executive Officer. "We are very excited as we move forward into 2019 which could be a transformational year for us, including the read outs from our Fabry trials and the potential for establishing the path for accelerated approval for PRX-102 with the FDA."

2018 Clinical and Corporate Highlights

Pegunigalsidase alfa (PRX-102) for the treatment of Fabry Disease

- Recently the Company held a very productive meeting with the FDA regarding the potential path for accelerated BLA approval for PRX-102.
- The FDA confirmed that the Company's PRX-102 program could rely on surrogate endpoints as part of the basis for a potential accelerated BLA approval.
- The FDA urged the Company to apply for a follow up Type C meeting as soon as possible to review with the agency the data and content of such potential accelerated filing application.
- The discussion with the FDA revolved around the data the Company has generated from all of its PRX-102 clinical trials to date, primarily the kidney biopsy results and the eGFR data, that could be included in the potential application for accelerated approval.
- In January 2018, the Company received fast track designation from the FDA for PRX-102.
- In May 2018, the Company reported on the baseline characteristics for its BALANCE phase III clinical trial for the treatment of Fabry disease highlighting that PRX-102 is less inhibited by preexisting neutralizing antibodies compared to Fabrazyme®, and, therefore, has the potential to attenuate renal decline and/or stabilize renal function in patients who have not had an optimal clinical response to Fabrazyme.
- In July 2018, the Company expanded its partnership with Chiesi Farmaceutici S.p.A., or Chiesi, to include exclusive U.S. rights for the development and commercialization of PRX-102. The terms of the agreement include an up-front payment of $25 million, up to $20 million in development costs, up to $760 million, in the aggregate, in regulatory and commercial milestone payments and tiered royalties ranging from 15 to 40%.
- In October 2018, the Company presented positive preliminary data from its BRIDGE phase III clinical trial for the treatment of Fabry disease indicating a significant improvement in kidney function in patients switched from agalsidase alfa (Replagal®) to PRX-102 at the 1st Canadian Symposium on Lysosomal Diseases.
- In December 2018, the enrollment for the BRIDGE phase III clinical trial for the treatment of Fabry disease was completed.
- As of today, the BALANCE trial is over 80% enrolled and the BRIGHT trial is over 90% enrolled.
- Based on the FDA discussion during our recent meeting we believe that the potential filing for accelerated approval might be based on data the Company has already generated in its clinical trials of PRX-102.
- Currently, substantially all patients treated in the BRIGHT trial have remained on the once-monthly 2mg/kg dosing regimen. All of the 13 patients that have completed the 12-month study have opted, together with their treating physician's advice, to continue with once-monthly dosing in an extension study rather than switching back to the 1mg/kg every two weeks regimen.

Oral antiTNF (OPRX-106) for Ulcerative Colitis

- Throughout 2018, the Company reported positive results from its phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis. Final results demonstrated as follows:
  - clinical response in 67% of patients and clinical remission in 28% of patients;
  - mucosal improvement in 61% of patients, with 33% achieving mucosal healing; and
  - 89% of the patients experienced a reduction in Mayo Score, and 61% of the patients experienced a reduction in endoscopic sub score.

- The Company is evaluating the best path forward which could include initiating next-stage development internally or collaborate with potential parties.

Alidornase alfa (PRX-110) for the treatment of Cystic Fibrosis

- In 2018, the Company received valuable feedback on PRX-110 from potential partners. While the data generated to date is very encouraging, further analysis will likely be required to maximize the potential value of this asset. Given the Company's focused cash utilization, it does not plan to conduct further development of PRX-110 at this time.

Full-Year 2018 Financial Results

- During the preparation of the 2018 annual report, the Company reevaluated its revenue recognition policies and determined that certain revenues generated under the Company's license agreements should be recognized for accounting purposes. Previously, the Company did not recognize those revenues.

- The Company recognized revenues from license and R&D services equal to $2.2 million, $2.8 million and $11.7 million over the first, second and third quarters of 2018, respectively. The restatement is expected to decrease the Company's loss for each of those periods.

- The Company recorded total revenues of $34.2 million during the year ended December 31, 2018, which was comprised of $9.0 million from selling goods and $25.2 million from license revenues, compared to $19.2 million from selling goods, and $1.8 million from license and R&D services for the same period of 2017.

- Research and development expenses for the year ended December 31, 2018, were $33.3 million, compared to $28.8 million for the same period of 2017. Selling, general and administrative expenses for the year ended December 31, 2018 were $10.9 million, compared to $11.5 million incurred during the same period of 2017.

- Operating loss for the year ended December 31, 2018 was $19.3 million compared to $34.5 million for the year ended December 31, 2017.

- For the year ended December 31, 2018, the Company reported a net loss of $26.5 million, or $0.18 per share, basic and diluted, compared to $45.4 million, excluding a one-time, non-cash net charge of $38.1 million in connection with the remeasurement of a derivative, or $0.35 per share, basic and diluted, for the same period of 2017.

- On December 31, 2018, the Company had $37.8 million of cash and cash equivalents, compared to $51.2 million on December 31, 2017, which is currently projected to fund operations into mid-2020. As of December 31, 2018, a total of $57.9 million aggregate principal amount of the Company's 7.5% convertible notes due November 2021 was outstanding.

Conference Call and Webcast Information

The Company will host a conference call on Monday, March 18, 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 9583103.

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; 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.

Investor Contact

Marcy Nanus, Managing Director
Solebury Trout
646-378-2927
mnanus@soleburytrout.com

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share amounts)

	December 31, 2017	2018
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 51,163	$ 37,808
Accounts receivable – Trade	1,721	4,729
Other assets	1,934	1,877
Inventories	7,833	8,569
Total current assets	62,651	52,983
NON-CURRENT ASSETS:		
Funds in respect of employee right upon retirement	1,887	1,758
Property and equipment, net	7,676	6,390
Total assets	$ 72,214	$ 61,131
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 7,521	$ 5,211
Other	9,310	10,274
Contracts liability		9,868
Convertible notes	5,921	

Total current liabilities	22,752	25,353
LONG TERM LIABILITIES:		
Convertible notes	46,267	47,966
Contracts liability	25,015	33,027
Liability for employee rights upon retirement	2,586	2,374
Other long term liabilities	5,051	5,292
Total long term liabilities	78,919	88,659
Total liabilities	101,671	114,012
COMMITMENTS		
CAPITAL DEFICIENCY:		
Common Stock, $0.001 par value:		
Authorized - as of December 31, 2017 and 2018, 250,000,000 shares; issued and outstanding, respectively - as of December 31, 2017 and 2018, 143,728,797 shares and 148,382,299 shares, respectively	144	148
Additional paid-in capital	266,495	269,524
Accumulated deficit	(296,096)	(322,553)
Total capital deficiency	(29,457)	(52,881)
Total liabilities net of capital deficiency	$ 72,214	$ 61,131

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

	Year ended December 31,		
	2016	**2017**	**2018**
REVENUES FROM SELLING GOODS	$ 9,199	$ 19,242	$ 8,978
REVENUES FROM LICENSE AND R&D SERVICES		1,836	25,262
COST OF GOODS SOLD	(8,398)	(15,231)	(9,302)
RESEARCH AND DEVELOPMENT EXPENSES	(30,412)	(32,170)	(35,534)
Less – grants	5,804	3,336	2,204
RESEARCH AND DEVELOPMENT EXPENSES, NET	(24,608)	(28,834)	(33,330)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(9,356)	(11,530)	(10,916)
OPERATING LOSS	(33,163)	(34,517)	(19,308)
FINANCIAL EXPENSES	(4,192)	(9,725)	(7,685)
FINANCIAL INCOME	589	188	536
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE	(6,473)	(38,061)	
(LOSS) GAIN ON EXTINGUISHMENT OF CONVERTIBLE NOTES	14,063	(1,325)	
FINANCIAL (EXPENSES) INCOME – NET	3,987	(48,923)	(7,149)
LOSS FROM CONTINUING OPERATIONS	(29,176)	(83,440)	(26,457)
LOSS FROM DISCONTINUED OPERATIONS	(189)		
NET LOSS FOR THE YEAR	$ (29,365)	$ (83,440)	$ (26,457)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED			
Loss from continuing operations	$ (0.29)	$ (0.64)	$ (0.18)
Loss from discontinued operations	(0.00)		
Net loss per share of common stock	$ (0.29)	$ (0.64)	$ (0.18)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE OF COMMON STOCK, BASIC AND DILUTED	101,387,704	131,085,958	147,135,182