Protalix BioTherapeutics Reports Second Quarter 2016 Financial Results

August 8, 2016

Patient Screening Underway for Fabry Phase III Clinical Trial

Data from the Cystic Fibrosis Phase II Clinical Trial Expected Around Year-End

CARMIEL, Israel, Aug. 08, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), today announced financial results for the fiscal quarter ended June 30, 2016.

"We remain focused on developing our clinical assets, and now have three drugs being evaluated in clinical trials," said Moshe Manor, Protalix's President and Chief Executive Officer. "We are currently screening patients in our phase III clinical trial of PRX-102 and anticipate the first patient being enrolled imminently."

Financial Results for the Period Ended June 30, 2016

- Net loss for the six months ended June 30, 2016 was $19.5 million, or $0.20 per share, an increase of $8.4 million, from $11.0 million, or $0.14 per share, for the same period of 2015. The increase is primarily due to the clinical advancement of PRX 102 for Fabry disease into the phase III clinical trial.
- Cash and cash equivalents as of June 30, 2016 were $54.6 million, which provides the Company with capital into 2018. Net cash used during the three months ended June 30, 2016 increased due to certain significant one-time expenditures that were made during the period, mainly in connection with the initiation of our phase III clinical trial for PRX 102 and other clinical programs.

Recent Company Highlights

- Initiated phase III clinical trial of PRX-102 for the treatment of Fabry disease after discussions with the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA); patient screening on-going in the initial sites recently opened and activated in the United States.
- Enrolled first patient in the Company's phase II proof of concept study of AIR DNase ^{TM}, or PRX-110, for the treatment of Cystic Fibrosis with top-line results on track for around year end.
- Protocol for PRX 106, the Company's oral antiTNF for the treatment of ulcerative colitis, was submitted in a number of sites, including in Europe; the study is expected to commence shortly.
- The Company's Fabry alfa galactosidase enzyme has been chosen for participation in the Horizon 2020 project, with expected funding of approximately $1.2M over the next three years. Horizon 2020 is an EU Research and Innovation program with nearly €80 billion of funding available with the aim to advance innovative ideas from the lab to the market. In this project, the PRX-102 enzyme will be nanoformulated in peptide-targeted nanoliposomes to analyze the facilitation of cell membrane crossing.

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(R). 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: PRX-102, 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; PRX-110 for the treatment of Cystic Fibrosis; and others.

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 "anticipate," "believe," "estimate," "expect," "plan" 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. 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: 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 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 the amount and sufficiency of our cash and cash equivalents; 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 commercialization efforts for taliglucerase alfa in Brazil; 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 release are valid only as of the date hereof and we disclaim any obligation to update this information.

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEET

(U.S. dollars in thousands)

(Unaudited)

	June 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 54,626	$ 76,374
Accounts receivable - Trade	1,493	-
Other assets	5,135	1,667
Inventories	6,067	5,767
Assets of discontinued operations	324	2,073
Total current assets	67,645	85,881
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,739	1,628
PROPERTY AND EQUIPMENT, NET	9,480	9,744
Total assets	$ 78,864	$ 97,253
LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,819	$ 3,629
Other	6,844	5,534
Deferred revenues	504	504
Liabilities of discontinued operations	293	1,568
Total current liabilities	11,460	11,235
LONG TERM LIABILITIES:		
Convertible notes	68,017	67,796
Deferred revenues	617	744
Liability for employee rights upon retirement	2,445	2,304
Promissory note	4,301	4,301
Total long term liabilities	75,380	75,145
Total liabilities	86,840	86,380
COMMITMENTS		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	(7,976)	10,873

Total liabilities and shareholders' equity (net of capital deficiency)	$ 78,864	$ 97,253

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except share and per share data)

(Unaudited)

	Six Months Ended		Three Months Ended	
	June 30, 2016	**June 30, 2015**	**June 30, 2016**	**June 30, 2015**
REVENUES	$ 2,448	$ 3,028	$ 1,769	$ 1,336
COST OF REVENUES	(2,198)	(507)	(1,675)	(225)
GROSS PROFIT	250	2,521	94	1,111
RESEARCH AND DEVELOPMENT EXPENSES (1)	(17,347)	(12,123)	(10,013)	(6,023)
Less – grants	3,503	2,457	2,194	1,329
RESEARCH AND DEVELOPMENT EXPENSES, NET	(13,844)	(9,666)	(7,819)	(4,694)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(4,201)	(3,823)	(2,206)	(2,001)
OPERATING LOSS	(17,795)	(10,968)	(9,931)	(5,584)
FINANCIAL EXPENSES	(1,805)	(1,799)	(901)	(642)
FINANCIAL INCOME	338	71	96	43
FINANCIAL EXPENSES – NET	(1,467)	(1,728)	(805)	(599)
LOSS FROM CONTINUING OPERATIONS	(19,262)	(12,696)	(10,736)	(6,183)
(LOSS) INCOME FROM DISCONTINUED OPERATIONS	(189)	1,653	(117)	1,112
NET LOSS FOR THE PERIOD	$ (19,451)	$ (11,043)	$ (10,853)	$ (5,071)
NET LOSS PER SHARE OF COMMON STOCK-BASIC AND DILUTED:				
Loss from continuing operations	(0.20)	(0.14)	(0.11)	(0.06)
Income from discontinued operations	0.00	0.02	0.00	0.01
Net loss per share of common stock	$ (0.20)	$ (0.12)	$ (0.11)	$ (0.05)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE– BASIC AND DILUTED:	99,737,348	93,418,666	99,758,511	93,635,213
(1) Includes share-based compensation	$ 366	$ 409	$ 128	$ 283
(2) Includes share-based compensation	$ 236	$ 564	$ 99	$ 271

Investor Contact

Marcy Nanus
The Trout Group, LLC
646-378-2927
mnanus@troutgroup.com

Protalix BioTherapeutics, Inc.