Protalix BioTherapeutics Reports 2016 Full Year Results and Provides Corporate Update

March 16, 2017

Current Cash is projected to Fund the Company through Three Clinical Trial Read-Outs and into 2019

CARMIEL, Israel, March 16, 2017 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT: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, 2016, and provided a corporate update.

"Recently, our Executive Vice President, Research and Development and two Principal Investigators that have been involved in our clinical trials of pegunigalsidase alfa for Fabry disease each gave presentations at the 13th Annual WORLDSymposium in San Diego on the data generated in our phase I/II clinical trial of pegunigalsidase alfa for the treatment of Fabry disease, and received very positive feedback from physicians and patient advocacy groups," said Moshe Manor, Protalix's President and Chief Executive Officer. "Looking ahead into 2017, we anticipate reporting results from both the phase II clinical trial of alidornase alfa for the treatment of Cystic Fibrosis and the phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis. In 2018, if we generate positive interim results from the pegunigalsidase phase II trial, we expect to begin the filing process for approval with the European Medicines Agency."

"Following a note exchange and private placement completed in December 2016, we have a strong cash position of approximately $63.3 million," said Yossi Maimon, Protalix's Vice President and Chief Financial Officer. "We anticipate these funds will be sufficient to fund our operations into 2019."

2016 and Recent Clinical and Corporate Highlights

Pegunigalsidase alfa (PRX-102) for Fabry Disease

- Announced positive six and twelve-month interim phase II data in March 2016 and reported final results of the trial in August 2016. This data was presented at the Society of Inborn Errors of Metabolism Annual Symposium in September 2016 and the 13th Annual WORLDSymposium in February 2017.

- Enrolled the first patient in a global phase III clinical trial to support filings in the United States (U.S.) and Europe in October 2016. Completion of enrollment is expected during the second half of 2017, with interim data analysis anticipated in 2018 to support European Medicines Agency and other regulatory filings outside of the United States, which comprise approximately two-thirds of the market.

Alidornase alfa (PRX-110) for Cystic Fibrosis

- Reported positive interim results from the first 13 patients treated in our phase II clinical trial in January 2017. Full results for all 16 patients enrolled in the study are expected in the first half of April 2017. Data from the study was accepted as an oral presentation at the 40th European Cystic Fibrosis Conference to be held in June 2017.

Oral anti-TNF (OPRX-106) for Ulcerative Colitis

- Enrolled the first patient in a phase II clinical trial in November 2016. Full results are expected around year end.

Alfataliglicerase for Gaucher Disease

- Granted pediatric approval of alfataliglicerase in Brazil for the treatment of Gaucher disease in children four years of age and older in November 2016.

- Received letter detailing and confirming purchases of approximately $24 million of drug product from Fundação Oswaldo Cruz (Fiocruz), an arm of the Brazilian Ministry of Health in December 2016.

Full-Year 2016 Financial Results

- For the year ended December 31, 2016, Protalix reported a net loss of $29.4 million, or $0.29 per share, basic and diluted, compared to a net loss of $27.3 million, or $0.29 per share, basic and diluted, for the year ended December 31, 2015 from continuing operations.

- Protalix recorded total revenues of $9.2 million for the full-year 2016, compared to $4.4 million during the same period of 2015. The increase is attributable mainly to increased sales of drug substance to Pfizer Inc. for inventory build up.

- Research and development expenses for full-year 2016 were $24.6 million, compared to $20.0 million for the same period

in 2015. Selling, general and administrative expenses for the full-year 2016 were $9.4 million, compared to $7.3 million incurred for the full-year 2015. The increase is mainly attributable to increased activities in Brazil.

- At December 31, 2016, Protalix had $63.3 million of cash and cash equivalents, compared to $76.4 million at December 31, 2015, which is currently projected to fund operations into 2019.

  - Protalix exchanged $54.1 million principal amount of the Company's $69.0 million 4.50% Senior Convertible Notes due 2018 for $40.2 million principal amount of newly issued 7.50% Senior Secured Convertible Notes due 2021 and approximately 23.8 million shares of common stock in December 2016.

  - Concurrent to the note exchange, the Company sold $22.5 million principal amount of the 7.50% Senior Secured Convertible Notes due 2021 in a private placement.

Conference Call and Webcast Information

The Company will host a conference call on Thursday, March 16, 2017, 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.

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.

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. Factors that might cause material differences include, among others: 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; 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 our ability to obtain stockholder approval prior to issuing 20% or more of our pre-refinancing outstanding shares of common stock, in compliance with certain listing standards of the NYSE MKT; 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.

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2015	2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 76,374	$ 63,281
Accounts receivable – Trade		693
Other assets	1,667	2,321
Inventories	5,767	5,245
Assets of discontinued operation	2,073	327
Total current assets	85,881	71,867
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,628	1,677
PROPERTY AND EQUIPMENT, NET	9,744	8,703
Total assets	$ 97,253	$ 82,247
LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,629	$ 4,007
Other	5,534	7,496
Convertible notes		53,872
Deferred revenues	504	837
Liabilities of discontinued operation	1,568	
Total current liabilities	11,235	66,212
LONG TERM LIABILITIES:		
Convertible notes	67,796	19,343
Deferred revenues	744	
Liability for employee rights upon retirement	2,304	2,348
Promissory note	4,301	4,301
Total long term liabilities	75,145	25,992
Total liabilities	86,380	92,204
COMMITMENTS (Note 6)		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):		
Common Stock, $0.001 par value:		
Authorized - as of December 31, 2015 and 2016, 150,000,000 and 250,000,000 shares; issued and outstanding, respectively - as of December 31, 2015 and 2016, 99,800,397 shares and 124,134,085 shares, respectively	100	124
Additional paid-in capital	194,064	202,575
Accumulated deficit	(183,291)	(212,656)
Total shareholders' equity (capital deficiency)	10,873	(9,957)
Total liabilities and shareholders' equity (net of capital deficiency)	$ 97,253	$ 82,247

PROTALIX BIOTHERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Year ended December 31,		
	2014	2015	2016
REVENUES	$ 3,523	$ 4,364	$ 9,199
COST OF REVENUES	(630)	(730)	(8,398)
GROSS PROFIT	2,893	3,634	801
RESEARCH AND DEVELOPMENT EXPENSES	(27,352)	(24,889)	(30,412)
Less – grants	5,128	4,864	5,804
RESEARCH AND DEVELOPMENT EXPENSES, NET	(22,224)	(20,025)	(24,608)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(9,228)	(7,279)	(9,356)
OPERATING LOSS	(28,559)	(23,670)	(33,163)
FINANCIAL EXPENSES	(4,935)	(3,735)	(10,665)
FINANCIAL INCOME	196	123	589
GAIN ON EXTINGUISHMENT OF CONVERTIBLE NOTES			14,063
FINANCIAL INCOME (EXPENSES) – NET	(4,739)	(3,612)	3,987
LOSS FROM CONTINUING OPERATIONS	(33,298)	(27,282)	(29,176)
(LOSS) INCOME FROM DISCONTINUED OPERATIONS	3,355	85,319	(189)
NET INCOME (LOSS) FOR THE YEAR	$ (29,943)	$ 58,037	$ (29,365)
NET INCOME (LOSS) PER SHARE OF COMMON STOCK – BASIC AND DILUTED			
Loss from continuing operations	$ (0.36)	$ (0.29)	$ (0.29)
Income from discontinued operations	0.04	0.90	(0.00)
Net (loss) income per share of common stock	$ (0.32)	$ 0.61	$ (0.29)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE OF COMMON STOCK, BASIC AND DILUTED	92,891,846	94,922,390	101,387,704

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Protalix BioTherapeutics, Inc.