Protalix BioTherapeutics Reports First Quarter 2015 Financial Results

May 7, 2015

- Losses narrowed by 19%

- Interim data and full results for PRX-102 expected in the Second Half of 2015

CARMIEL, Israel, May 7, 2015 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), today reported financial results for the quarter ended March 31, 2015.

"We continue to execute on our strategy for accelerated growth, which centers on developing products with clinically superior profiles and clear competitive advantages," said Moshe Manor, Protalix's President and Chief Executive Officer. "We have a number of key milestones anticipated to occur over the next few quarters that have the potential to create significant shareholder value. We plan to announce interim and full results from our phase I/II clinical trial of PRX-102 for the treatment of Fabry disease during the second half of 2015. Around year-end, we anticipate holding an end of Phase II meeting with the U.S. Food and Drug Administration for PRX-102, and initiating proof of concept clinical trials in patients for both oral antiTNF and AIR DNase. In the first half of 2016, we expect to launch a pivotal head-to-head phase III clinical trial of PRX-102 for the treatment of Fabry disease, and report results from our oral antiTNF and AIR DNase trials."

Financial Results for the Quarter Ended March 31, 2015

- Net loss narrowed to $6.0 million, or $0.06 per share, for the first quarter of 2015 down $1.3 million or 19% from $7.3 million, or $0.08 per share, for the same period in 2014.
- Total revenues for the first quarter of 2015 were $4.4 million compared to $6.7 million for the first quarter of 2014. The decrease resulted primarily from a decrease of $1.8 million of products sold in Brazil and a decrease of $597,000 of products we delivered at cost to Pfizer Inc. under our license agreement.
    - During April 2015, we delivered an additional $1.3 million of products to Brazil.
- Revenue from our share of net income from the collaboration under the Pfizer agreement increased 3% to $705,000 for the first quarter 2015 compared to $687,000 for the first quarter of 2014. The increase resulted primarily from the $5.4 million in revenues generated by Pfizer, mainly in the United States, during the three months ended March 31, 2015 compared to $4.0 for the three months ended March 31, 2014.
- Cost of revenues was $2.4 million for the first quarter of 2015, a decrease of $1.7 million or 41%, compared to $4.1 million for the same period in 2014.
- Selling, general and administrative expenses decreased 48% to $1.9 million for the first quarter of 2015 compared to $3.7 million for first quarter of 2014. The decrease resulted primarily from a decrease of $1.0 million in salaries expenses, mainly due to bonuses that were paid during the first quarter of 2014, and the devaluation of the New Israeli Shekel against the U.S. dollar during the period.
- Cash and cash equivalents as of March 31, 2015 were $48.0 million representing cash consumption for the quarter of approximately $6.8 million.

First Quarter and Recent Operational and Clinical Highlights

- In January 2015, we announced a new strategy for accelerated growth focused on developing products with potentially clinically superior profiles that offer a clear competitive advantage over other products.
- For PRX-102, we announced completion of enrollment in our Fabry disease trial on February 2, 2015. We expect to release interim data from the 1mg/kg dose cohort of the trial during the third quarter of 2015, with final results to be released by year-end. We anticipate holding an end of Phase II meeting with the U.S. Food and Drug Administration around year-end and intend to launch a phase III head-to-head pivotal trial comparing PRX-102 to a commercially available enzyme replacement therapy for the treatment of Fabry disease in early 2016.
- For PRX-106, our oral antiTNF product candidate, a phase I trial is currently on-going. We expect to select an indication for the product candidate and to initiate a proof of concept efficacy study around year-end with results expected in the first half of 2016.
- We are also currently evaluating clinical sites for our planned AIR DNase clinical trial, which is expected to first enroll healthy volunteers and then cystic fibrosis patients. The trial is being designed to run as a head-to-head study comparing AIR DNase to Pulmozyme. We expect that this trial will be launched around year-end with results to be released in the first half of 2016.

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, by Israel's Ministry of Health in September 2012, by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013, by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in April 2013, by the Australian Therapeutic Goods Administration(TGA) in May 2014 and by the regulatory authorities of other countries. Marketing applications for taliglucerase alfa have been filed in additional territories as well. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of taliglucerase alfa, excluding Israel and 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; PRX-112, an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, also for the treatment of Gaucher disease; PRX-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: risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations under our supply and technology transfer; risks related to the commercialization efforts for taliglucerase alfa in the United States, Israel, Brazil, Canada, Australia and other countries; failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; 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; 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 SHEETS

(U.S. dollars in thousands)

(Unaudited)

	March 31, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 47,958	$ 54,767
Accounts receivable - Trade	1,816	1,884
Other assets	2,931	2,202
Inventories	6,879	6,667
Total current assets	59,584	65,520
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,520	1,555
PROPERTY AND EQUIPMENT, NET	10,839	11,282
DEFERRED CHARGES	105	113
Total assets	$ 72,048	$ 78,470
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,195	$ 3,951

Other	14,282	15,496
Deferred revenues	7,072	6,763
Total current liabilities	26,549	26,210
LONG TERM LIABILITIES:		
Convertible notes	67,566	67,464
Deferred revenues	36,890	37,232
Liability in connection with collaboration operation		912
Liability for employee rights upon retirement	2,197	2,253
Total long term liabilities	106,653	107,861
Total liabilities	133,202	134,071
COMMITMENTS		
CAPITAL DEFICIENCY	(61,154)	(55,601)
Total liabilities net of capital deficiency	$ 72,048	$ 78,470

PROTALIX BIOTHERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three Months Ended	
	March 31, 2015	**March 31, 2014**
REVENUES	$ 4,392	$ 6,696
COMPANY'S SHARE IN COLLABORATION AGREEMENT	705	687
COST OF REVENUES	(2,400)	(4,073)
GROSS PROFIT	2,697	3,310
RESEARCH AND DEVELOPMENT EXPENSES (1)	(6,762)	(8,152)
Less – grants and reimbursements	1,135	2,085
RESEARCH AND DEVELOPMENT EXPENSES, NET	(5,627)	(6,067)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(1,913)	(3,711)
OPERATING LOSS	(4,843)	(6,468)
FINANCIAL EXPENSES	(1,157)	(915)
FINANCIAL INCOME	28	38
FINANCIAL EXPENSES – NET	(1,129)	(877)
NET LOSS FOR THE PERIOD	$ (5,972)	$ (7,345)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ 0.06	$ 0.08
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	93,200,739	92,686,638
(1) Includes share-based compensation	126	428
(2) Includes share-based compensation	293	242

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Protalix BioTherapeutics, Inc.