Protalix BioTherapeutics Reports Second Quarter 2015 Financial Results

August 10, 2015

Net Losses Narrowed With Clinical Progress in All Three Product Candidates

CARMIEL, Israel, Aug. 10, 2015 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), today reported financial results for the second quarter of 2015.

"We recently reported positive Phase I results for PRX-106 (oral Anti-TNF), with exciting results showing biological activity in the gut and activation of regulatory T cells," said Moshe Manor, Protalix's President and Chief Executive Officer. "We look forward to selecting an indication and moving this program into a proof of concept trial around year-end. Additionally, we anticipate interim results for PRX-102 for the treatment of Fabry disease in September, including 6-month data for the 1mg/kg dose group and 12-month data for the 0.2mg/kg group. We also expect to initiate a proof of concept study for AIR DNase™ in Cystic Fibrosis patients early next year."

Financial Results for the Period Ended June 30, 2015

- Net loss narrowed to $5.1 million, or $0.05 per share, for the three months ended June 30, 2015, down $1.0 million, or 17%, from $6.1 million, or $0.07 per share, for the same period in 2014.
- Total revenues for the three months ended June 30, 2015 were $3.8 million compared to $2.4 million in the same period in 2014. The increase resulted primarily from an increase of $1.3 million in sales in Brazil compared to the same period in 2014.
- Revenue from the Company's share of net income from the collaboration under the Pfizer agreement increased by $573,000, to $834,000 for the three months ended June 30, 2015 compared to $261,000 for the same period in 2014.
- Total worldwide sales of Elelyso™ during the six months ended June 30, 2015 were $15.8 million, an increase of $2.7 million, or 21%, compared to worldwide sales of $13.1 million for the six months ended June 30, 2014.
- Cost of revenues was $4.4 million for the six months ended June 30, 2015 compared to $5.7 million for the same period in 2014.
- Selling, general and administrative expenses decreased 24% to $4.0 million for the six months ended June 30, 2015 compared to $5.3 million for six months ended June 30, 2014. The decrease resulted primarily from a decrease of $1.0 million in salaries expenses, and the devaluation of the New Israeli Shekel against the U.S. Dollar during the period.
- Cash and cash equivalents as of June 30, 2015 were $43.2 million representing an average quarterly cash consumption of approximately $5.8 million, a $1.9 million decrease compared to the same period in 2014.

Second Quarter and Recent Clinical and Corporate Highlights

- The Company is actively discussing with Fundação Oswaldo Cruz ("Fiocruz") potential actions that Fiocruz may take to comply with its purchase obligations under the Tech Transfer and Supply agreement since, as of July 31, 2015, Fiocruz has not yet achieved its minimum purchase obligation thereunder. The Company is, at this time, continuing to supply Uplyso™ to Fiocruz under the agreement, and patients continue to be treated with Uplyso in Brazil, as approximately 10% of adult Gaucher patients in Brazil are currently treated with Uplyso.
- Ex-vivo efficacy studies in Cystic Fibrosis patients' sputum DNase show greater efficiency of AIR DNase compared to Pulmozyme® by reducing sputum viscoelasticity and DNA content. Toxicology studies of AIR DNase are being concluded to support the initiation of a phase I clinical study in healthy volunteers during the next quarter followed by a proof of concept study in Cystic Fibrosis patients early next year.
- Phase I data for PRX-106 received in July demonstrate a favorable safety profile as well as biological activity in the gut and the activation of regulatory T cells.
- The Company has commenced upgrading its manufacturing facility to become a multiproduct facility and support the manufacturing of PRX-102, in addition to taliglucerase alfa in a commercial scale. The Company expects that the upgraded

facility will be able to support the worldwide marketing needs of both products. Due to the Company's unique platform technology, the Company does not expect that these efforts will entail additional capital expenditures.

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 and related milestones under our supply and technology transfer agreement; 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: 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; 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)

	June 30, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$43,238	$54,767
Accounts receivable - Trade	1,936	1,884
Other assets	2,326	2,202
Inventories	6,368	6,667
Total current assets	53,868	65,520
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,596	1,555
PROPERTY AND EQUIPMENT, NET	10,392	11,282
DEFERRED CHARGES	98	113
Total assets	$65,954	$78,470

LIABILITIES NET OF CAPITAL DEFICIENCY

CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$4,275	$3,951
Other	14,316	15,496
Deferred revenues	6,928	6,763
Total current liabilities	25,519	26,210
LONG TERM LIABILITIES:		
Convertible notes	67,670	67,464
Deferred revenues	35,614	37,232
Liability in connection with collaboration operation		912
Liability for employee rights upon retirement	2,288	2,253
Total long term liabilities	105,572	107,861
Total liabilities	131,091	134,071
COMMITMENTS		
CAPITAL DEFICIENCY	(65,137)	(55,601)
Total liabilities net of capital deficiency	$65,954	$78,470

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, 2015	**June 30, 2014**	**June 30, 2015**	**June 30, 2014**
REVENUES	$8,174	$9,121	$3,782	$2,425
COMPANY'S SHARE IN COLLABORATION AGREEMENT	1,539	948	834	261
COST OF REVENUES	(4,439)	(5,678)	(2,039)	(1,605)
GROSS PROFIT	5,274	4,391	2,577	1,081
RESEARCH AND DEVELOPMENT EXPENSES (1)	(13,233)	(15,228)	(6,471)	(7,076)
Less – grants and reimbursements	2,649	4,199	1,514	2,114
RESEARCH AND DEVELOPMENT EXPENSES, NET	(10,584)	(11,029)	(4,957)	(4,962)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(4,005)	(5,277)	(2,092)	(1,566)
OPERATING LOSS	(9,315)	(11,915)	(4,472)	(5,447)
FINANCIAL EXPENSES	(1,799)	(1,789)	(642)	(874)
FINANCIAL INCOME	71	240	43	202
FINANCIAL EXPENSES – NET	(1,728)	(1,549)	(599)	(672)
NET LOSS FOR THE PERIOD	$(11,043)	$(13,464)	$(5,071)	$(6,119)
NET LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED:	$(0.12)	$(0.15)	$(0.05)	$(0.07)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED:	93,418,666	92,754,640	93,635,213	92,820,897
(1) Includes share-based compensation	409	591	283	163
(2) Includes share-based compensation	564	(14)	271	(256)

CONTACT: Investor Contact

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

Protalix BioTherapeutics, Inc.