Protalix BioTherapeutics Reports First Quarter 2016 Financial Results and Provides Corporate Update

May 9, 2016

Advanced Discussions with FDA regarding SPA for Phase III Clinical Trial of PRX-102 Expected to Commence around Mid-Year

Phase II Clinical Trial of PRX-110 in Cystic Fibrosis Patients to commence by Mid-Year

Phase II Clinical Trial of PRX-106 in Ulcerative Colitis Patients to commence around Mid-Year

Strong Cash Position; finances the Company into 2018, through significant milestones

CARMIEL, Israel, May 09, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), today announced financial results for the fiscal quarter ended March 31, 2016 and provided a corporate update.

“Over the past few months, Protalix has made great strides towards moving PRX-102 into phase III development,” said Moshe Manor, Protalix’s President and Chief Executive Officer. “We filed a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA), and have since been in close contact with the agency to implement its feedback. We anticipate completing the SPA with the FDA around mid-year 2016, and announcing the commencement of our phase III clinical development program for PRX-102 shortly thereafter. Additionally, we met with the European Medicines Agency (EMA), and we expect to reach and announce a clear path forward for PRX-102 in the European Union as well by mid-year.”

"We are also very excited about the advancement of our PRX-110 and PRX-106 product candidates into advanced clinical trials in patients. Given results from earlier trials, both drug candidates have the potential to bring significant benefit to currently underserved patient populations worldwide."

Financial Results for the Period Ended March 31, 2016

- Net loss for the quarter was $8.6 million, or $0.09 per share, for the three months ended March 31, 2016, an increase of $2.6 million, or 43%, from $6.0 million, or $0.06 per share, for the same period in 2015.
- Total operating expenses increased to $8.0 million for the three months ended March 31, 2016 compared to $6.8 million for three months ended March 31, 2015, primarily due to the advancement of our entire pipeline into more advanced clinical stages.
- Cash and cash equivalents as of March 31, 2016 were $66.7 million, which we expect to be sufficient to finance our activities into 2018 through significant milestones.

First Quarter Clinical and Corporate Highlights

- Positive six and twelve month interim clinical data for PRX-102 for the treatment of Fabry Disease were presented at the 12th Annual WORLD*Symposium*™ 2016 held in San Diego, CA. PRX-102 demonstrated effectiveness across all disease parameters including cardiac and kidney functions and showed very low levels of antibody formation.
- SPA submitted to the FDA in connection with PRX-102 for the treatment of Fabry disease.
- Successfully completed phase I clinical trial of PRX-110 in 18 healthy volunteers with clean safety profile.
- Received approval from the Israeli Ministry of Health of the protocol for our phase II clinical trial of PRX-110 in Cystic Fibrosis patients. We anticipate initiation of the study before mid-year.
- Proposed protocol for a phase II clinical trial of PRX-106 in Ulcerative Colitis patients in Israel filed with the Israeli Ministry of Health; the protocol is expected to be filed with a number of European ethics committees shortly, as well. We expect to announce initiation of the study during the third quarter.

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)

	March 31, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 66,669	$ 76,374
Other assets	2,945	1,667
Inventories	5,737	5,767
Assets of discontinued operation	918	2,073
Total current assets	76,269	85,881
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,731	1,628
PROPERTY AND EQUIPMENT, NET	9,310	9,744
Total assets	$ 87,310	$ 97,253
LIABILITIES AND SHAREHOLDERS’ EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,890	$ 3,629
Other	4,757	5,534
Deferred revenues	504	504
Liabilities of discontinued operation	128	1,568
Total current liabilities	9,279	11,235
LONG TERM LIABILITIES:		
Convertible notes	67,906	67,796
Deferred revenues	744	744
Liability for employee rights upon retirement	2,430	2,304
Promissory note	4,301	4,301

Total long term liabilities	75,381	75,145
Total liabilities	84,660	86,380
COMMITMENTS		
SHAREHOLDERS' EQUITY	2,650	10,873
Total liabilities and shareholders' equity	$ 87,310	$ 97,253

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

	Three Months Ended	
	March 31, 2016	**March 31, 2015**
REVENUES	$ 679	$ 1,692
COST OF REVENUES	(523)	(282)
GROSS PROFIT	156	1,410
RESEARCH AND DEVELOPMENT EXPENSES (1)	(7,334)	(6,100)
Less – grants	1,309	1,128
RESEARCH AND DEVELOPMENT EXPENSES, NET	(6,025)	(4,972)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(1,995)	(1,822)
OPERATING LOSS	(7,864)	(5,384)
FINANCIAL EXPENSES	(904)	(1,157)
FINANCIAL INCOME	242	28
FINANCIAL EXPENSES – NET	(662)	(1,129)
LOSS FROM CONTINUING OPERATIONS	(8,526)	(6,513)
INCOME (LOSS) FROM DISCONTINUED OPERATIONS	(72)	541
NET LOSS FOR THE PERIOD	$ (8,598)	$ (5,972)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED		
Loss from continuing operations	$ (0.09)	$ (0.07)
Income from discontinued operations	(0.00)	0.01
Net loss per share of common stock	$ (0.09)	$ (0.06)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	99,715,625	93,200,739
(1) Includes share-based compensation	238	126
(2) Includes share-based compensation	137	293

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