# Protalix BioTherapeutics Provides Update and Reports 2016 Third Quarter Results

November 9, 2016

*Patient Enrollment Ongoing for Phase III Fabry Clinical Trial with approximately 10 Patients Currently in Evaluation and Screening Stages*

*Enrollment for the Phase II Cystic Fibrosis Clinical Trial in Final Stages with Results Expected around Year-End*

*Phase II Ulcerative Colitis Study Expected to Commence Before Year-End*

CARMIEL, Israel, Nov. 09, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX) today announced financial results for the fiscal quarter ended September 30, 2016 and provided a business update.

"We are very excited by the progress made with our product candidates," said Moshe Manor, Protalix's President and Chief Executive Officer. "We are currently enrolling patients in seven sites globally for our phase III clinical trial of PRX-102 for the treatment of Fabry disease, and we are finalizing enrollment in our phase II clinical trial of AIR DNase™ (PRX-110) for the treatment of Cystic Fibrosis (CF)."

**Financial Results for the Quarter Ended September 30, 2016**

- Net loss for the quarter was $7.3 million, or $0.07 per share, for the three months ended September 30, 2016, an increase of $3.5 million from $3.8 million, or $0.04 per share, for the same period in 2015. The increase is primarily the result of the initiation during 2016 of both our phase III clinical trial of Fabry disease and our phase II clinical trial of CF.
- Total operating expenses were $7.1 million for the three months ended September 30, 2016 compared to $6.1 million for three months ended September 30, 2015.
- Cash and cash equivalents as of September 30, 2016 were $51.3 million, which provides the Company with capital into 2018.

**Recent Company Highlights and Business Update**

- First patient was enrolled in the Company's phase III clinical trial of PRX-102 for the treatment of Fabry disease, with approximately 10 patients in the evaluation or screening process across seven sites.
- Enrollment in the Company's phase II clinical trial of AIR DNase for the treatment of CF is in its final stages, with top-line results expected around year-end.
- Sites are being initiated for the Company's phase II clinical trial of Oral Anti-TNF, or OPRX-106, for the treatment of Ulcerative Colitis, with patient enrollment expected to commence before year-end.
- Advanced, direct negotiations with the Brazilian Ministry of Health are in process for the supply of a significant amount of vials of alfataliglicerase for Gaucher disease in 2017. If these negotiations are concluded successfully, the Company would expect to recognize markedly higher revenues than those that the Company has reported to date.
- Discussions are ongoing with potential collaboration partners for AIR DNase and Oral Anti-TNF.

**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 related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase, and our commercialization efforts for alfataliglicerase in Brazil generally; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our 2018 convertible notes or any other indebtedness; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; 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)

| | September 30, 2016 | December 31, 2015 |
|---|---|---|
| **ASSETS** | | |
| **CURRENT ASSETS:** | | |
| Cash and cash equivalents | $ 51,320 | $ 76,374 |
| Accounts receivable - Trade | 2,096 | - |
| Other assets | 1,045 | 1,667 |
| Inventories | 4,860 | 5,767 |
| Assets of discontinued operations | 327 | 2,073 |
| Total current assets | 59,648 | 85,881 |
| **FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT** | 1,686 | 1,628 |
| **PROPERTY AND EQUIPMENT, NET** | 9,140 | 9,744 |
| Total assets | $ 70,474 | $ 97,253 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)** | | |
| **CURRENT LIABILITIES:** | | |
| Accounts payable and accruals: | | |
| Trade | $ 3,989 | $ 3,629 |
| Other | 5,840 | 5,534 |
| Deferred revenues | 504 | 504 |
| Liabilities of discontinued operations | - | 1,568 |
| Total current liabilities | 10,333 | 11,235 |
| **LONG TERM LIABILITIES:** | | |
| Convertible notes | 68,129 | 67,796 |
| Deferred revenues | 453 | 744 |
| Liability for employee rights upon retirement | 2,361 | 2,304 |
| Promissory note | 4,301 | 4,301 |
| Total long term liabilities | 75,244 | 75,145 |
| Total liabilities | 85,577 | 86,380 |
| **COMMITMENTS** | | |

| | | |
|---|---|---|
| **SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)** | (15,103) | 10,873 |
| Total liabilities and shareholders' equity (net of capital deficiency) | $ 70,474 | $ 97,253 |

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

| | Nine Months Ended | | Three Months Ended | |
|---|---|---|---|---|
| | **September 30, 2016** | **September 30, 2015** | **September 30, 2016** | **September 30, 2015** |
| **REVENUES** | $ 7,118 | $ 4,364 | $ 4,670 | $ 1,336 |
| **COST OF REVENUES** | (6,446) | (730) | (4,248) | (223) |
| **GROSS PROFIT** | 672 | 3,634 | 422 | 1,113 |
| **RESEARCH AND DEVELOPMENT EXPENSES (1)** | (23,700) | (17,191) | (6,353) | (5,068) |
| **Less – grants** | 4,800 | 3,573 | 1,297 | 1,116 |
| **RESEARCH AND DEVELOPMENT EXPENSES, NET** | (18,900) | (13,618) | (5,056) | (3,952) |
| **SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)** | (6,215) | (5,986) | (2,014) | (2,163) |
| **OPERATING LOSS** | (24,443) | (15,970) | (6,648) | (5,002) |
| **FINANCIAL EXPENSES** | (2,715) | (2,805) | (910) | (1,030) |
| **FINANCIAL INCOME** | 606 | 64 | 268 | 17 |
| **FINANCIAL EXPENSES – NET** | (2,109) | (2,741) | (642) | (1,013) |
| **LOSS FROM CONTINUING OPERATIONS** | (26,552) | (18,711) | (7,290) | (6,015) |
| **(LOSS) INCOME FROM DISCONTINUED OPERATIONS** | (189) | 3,848 | - | 2,195 |
| **NET LOSS FOR THE PERIOD** | $ (26,741) | $ (14,863) | $ (7,290) | $ (3,820) |
| **NET LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED:** | | | | |
| **Loss from continuing operations** | (0.27) | (0.20) | (0.07) | (0.06) |
| **Income (loss) from discontinued operations** | - | 0.04 | - | 0.02 |
| **Net loss per share of common stock** | $ (0.27) | $ (0.16) | $ (0.07) | $ (0.04) |
| **WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED:** | 99,766,245 | 93,599,414 | 99,821,970 | 93,943,772 |
| **(1) Includes share-based compensation** | $ 448 | $ 667 | $ 82 | $ 258 |
| **(2) Includes share-based compensation** | $ 317 | $ 752 | $ 81 | $ 188 |

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