UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): November 9, 2015

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Florida	**001-33357**	**65-0643773**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2 Snunit Street **Science Park, POB 455** **Carmiel, Israel** **(Address of principal executive offices)**	**20100** **(Zip Code)**

Registrant's telephone number, including area code +972-4-988-9488

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02. Results of Operations and Financial Condition

On November 9, 2015, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2015. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated November 9, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

PROTALIX BIOTHERAPEUTICS, INC.

Date: November 9, 2015

By: /s/ Moshe Manor
Name: Moshe Manor
Title: President and
Chief Executive Officer

Protalix BioTherapeutics Reports Third Quarter 2015 Financial Results
Net losses narrowed

Recent sale of Company's Share in Collaboration and Equity Issuance to Pfizer Yielding a Total of $46 Million to Help Aggressively Push all Three Product Candidates

CARMIEL, Israel, November 9, 2015 -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), today reported financial results for the third quarter of 2015.

“The past three months have been very exciting for the company with positive clinical data shown in PRX-102 and PRX-106,” said Moshe Manor, Protalix’s President and Chief Executive Officer. “We continued to advance our pipeline, and selling our share in the collaboration of Elelyso™ to Pfizer will allow us to continue to move forward, stronger than before. We look forward to reporting on our upcoming End of Phase II meeting with the FDA, and moving closer to creating a better option for the Fabry community.”

Financial Results for the Period Ended September 30, 2015

• Net loss narrowed to $3.8 million, or $0.04 per share, for the three months ended September 30, 2015, down $4.2 million, or 52%, from $8.0 million, or $0.09 per share, for the same period in 2014.

• Total revenues for the three months ended September 30, 2015 were $4.3 million compared to $2.4 million in the same period in 2014. The increase resulted primarily from $1.3 million of Uplsyo™ sales in Brazil.

• Revenue from the Company’s share of net income from the collaboration under the Pfizer agreement increased by $234,000, to $1.5 million for the three months ended September 30, 2015, compared to $1.3 million for the same period in 2014.

• Cost of revenues was $6.8 million for the nine months ended September 30, 2015 compared to $7.5 million for the same period in 2014.

• Selling, general and administrative expenses decreased 14% to $6.3 million for the nine months ended September 30, 2015 compared to $7.3 million for nine months ended September 30, 2014.

• Cash and cash equivalents as of September 30, 2015 were $34.2 million representing an average quarterly cash consumption of approximately $6.7 million, a $1.9 million decrease compared to the same period in 2014. The cash balance does not include the $46.0 million from the sale of our share in collaboration as detailed below.

Third Quarter and Recent Clinical and Corporate Highlights

• The Company recently sold its share in collaboration for Elelyso for $36.0 million and issued approximately 6% of its outstanding shares to Pfizer for additional $10.0 million. The *pro forma* cash balance of approximately $80.0 million as of September 30, 2015, after giving effect to the transaction allows us to aggressively push our clinical pipeline forward and concentrate on our new strategy of developing superior biologics.

• Results from the 12 month study of the 0.2mg, lowest dose of PRX-102 in Fabry patients showed significant improvement across multiple parameters. Most importantly, the clinical data on Kidney Function was promising with reversal of the eGFR slope. The low incidence of antibody formation leads to full active dose availability for effective treatment.

• Interim clinical data of the 1mg dose of PRX-102 in Fabry patients demonstrated significant improvement across all disease parameters coupled with an excellent safety profile. Only one patient experienced hypersensitivity, and approximately 19% of the patients developed antibodies. Additionally, PRX-102 demonstrated a reduction in renal peritubular capillary Gb3 of 86%.

• The Company expects to report on its End of Phase II meeting with the FDA before the end of the year and provide additional guidance on its plans regarding its plans for a pivotal phase III clinical trial of PRX-102 to support drug approval.

• The Company is currently producing Fabry drug substance for its planned phase III trial as part of the process of converting its current approved manufacturing facility to an approved multi product facility, thereby introducing potentially significant operational savings.

• The Company is currently planning an Inflammatory Bowel Disease (IBD) proof of concept study in patients for PRX-106 which the Company anticipates commencing by the first quarter of 2016. The Company is also exploring Non Alcoholic Steato Hepatits (NASH) as a candidate for PRX-106. In preclinical studies, PRX-106 alleviated immune-mediated hepatitis and reduced interferon gamma levels in ConA inflammatory mouse models. Further, the drug was shown to alleviate liver damage and reduce liver necrosis and reduce ALT and AST which led to an improvement in liver biopsies.

• The Company completed a toxicity study in PRX-110 AIR DNase™ for the treatment of Cystic Fibrosis. The toxicity study was designed to support a phase I clinical trial, which is scheduled to start before the end of the year, to be followed by a proof of concept study in Cystic Fibrosis patients during 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 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; PRX-112, an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, 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 Brazil; 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.

Investor Contact

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Source: Protalix BioTherapeutics, Inc.

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 34,248	$ 54,767
Accounts receivable - Trade	4,573	1,884
Other assets	2,716	2,202
Inventories	6,339	6,667
Total current assets	47,876	65,520
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,569	1,555
PROPERTY AND EQUIPMENT, NET	9,957	11,282
DEFERRED CHARGES	90	113
Total assets	$ 59,492	$ 78,470
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,057	$ 3,951
Other	11,946	15,496
Deferred revenues	6,850	6,763
Total current liabilities	22,853	26,210
LONG TERM LIABILITIES:		
Convertible notes	67,774	67,464
Deferred revenues	35,127	37,232
Liability in connection with collaboration operation		912
Liability for employee rights upon retirement	2,249	2,253
Total long term liabilities	105,150	107,861
Total liabilities	128,003	134,071
COMMITMENTS		
CAPITAL DEFICIENCY	(68,511)	(55,601)
Total liabilities net of capital deficiency	$ 59,492	$ 78,470

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, 2015	September 30, 2014	September 30, 2015	September 30, 2014
REVENUES	$ 12,475	$ 11,517	$ 4,301	$ 2,396
COMPANY'S SHARE IN COLLABORATION AGREEMENT	3,084	2,259	1,545	1,311
COST OF REVENUES	(6,785)	(7,476)	(2,346)	(1,798)
GROSS PROFIT	8,774	6,300	3,500	1,909
RESEARCH AND DEVELOPMENT EXPENSES (1)	(18,493)	(23,280)	(5,260)	(8,052)
Less – grants and reimbursements	3,856	6,146	1,207	1,947
RESEARCH AND DEVELOPMENT EXPENSES, NET	(14,637)	(17,134)	(4,053)	(6,105)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(6,259)	(7,289)	(2,254)	(2,012)
OPERATING LOSS	(12,122)	(18,123)	(2,807)	(6,208)
FINANCIAL EXPENSES	(2,805)	(3,490)	(1,030)	(1,851)
FINANCIAL INCOME	64	139	17	49
FINANCIAL EXPENSES – NET	(2,741)	(3,351)	(1,013)	(1,802)
NET LOSS FOR THE PERIOD	$ (14,863)	$ (21,474)	$ (3,820)	$ (8,010)
NET LOSS PER SHARE OF COMMON STOCK - BASIC AND DILUTED:	$ (0.16)	$ (0.23)	$ (0.04)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED:	93,599,414	92,828,851	93,943,772	92,971,572
(1) Includes share-based compensation	667	764	258	173
(2) Includes share-based compensation	752	(81)	188	(67)