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): March 8, 2016

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 March 8, 2016, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the 2015 fiscal year. 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 March 8, 2016.

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: March 8, 2016

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

Exhibit 99.1

Protalix BioTherapeutics Reports Fiscal Year 2015 Financial Results and Provides Corporate Update

Net Income of $58 Million Generated mainly due to the Sale of Our Share in Collaboration to Pfizer

Strong Cash Position of $76.3 Million Projected to Fund Operations into 2018

Special Protocol Assessment for Phase III Clinical Trials of Fabry Disease Filed

Fabry Disease Phase III Trials Expected to Start in First Half of 2016

Two Proof of Concept Studies in Patients of AIR DNase™ and Oral antiTNF Planned to Start in Mid 2016

CARMIEL, Israel, March 8, 2016 -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), today reported financial results for the 2015 fiscal year.

“A number of corporate and clinical milestones were achieved in 2015, and additional milestones are expected during 2016. Most significantly, we reported meaningful positive interim results for PRX-102 for the treatment of Fabry disease, and are now moving forward to secure a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA) ahead of initiating our phase III clinical trials,” said Moshe Manor, Protalix’s President and Chief Executive Officer. “Over the next couple of months, we anticipate commencing the Fabry trials in addition to two proof of concept trials; one for AIR DNase™ in cystic fibrosis patients and another for oral antiTNF in ulcerative colitis patients. Given the sale of our rights to Elelyso™ to Pfizer Inc., we are now well capitalized to execute on our pipeline programs.”

Financial Results for Continuing Operations for the Fiscal Year Ended December 31, 2015

- Total revenues for the year ended December 31, 2015 increased 24% to $4.4 million compared to $3.5 million for the same period of 2014. All revenues were generated from products sold in Brazil, which remains a continuing operation for our company.
- Research and development expenses, net for the full fiscal year 2015 were $20.0 million compared to $22.2 million for the full fiscal year 2014.
- Selling, general and administrative expenses for the year ended December 31, 2015 decreased $1.9 million to $7.3 million compared to $9.2 million for the same period of 2014.
- Net loss from continuing operations for the year ended December 31, 2015 was $27.3 million, or $0.29 per share, compared to $33.3 million, or $0.36 per share, for the year ended December 31, 2014.

Financial Results for Discontinued Operations for the Fiscal Year Ended December 31, 2015

On October 13, 2015, we announced the sale to Pfizer of our share in the collaboration agreement for Elelyso, and a 6% stake in our company, for a total of $46.0 million. We treated all Elelyso-related activities sold to Pfizer as discontinued operations.

- Net income from discontinued operations for the full fiscal year 2015 was $85.3 million, or $0.90 per share, compared to $3.4 million, or $0.04 per share, for the full fiscal year 2014.

Net Income of $85.3 million from discontinued operations for fiscal year 2015 includes a $40.0 million gain from the sale of the activity, recognition of deferred revenues in the amount of $41.8 million and other Elelyso-related revenues and expenses.

Total net income, from both continuing and discontinued operations, for the year ended December 31, 2015 was $58.0 million, or $0.61 per share, compared to a net loss of $29.9 million, or $0.32 per share, for the year ended December 31, 2014.

Cash and cash equivalents as of December 31, 2015 were $76.4 million, compared to $54.8 million as of December 31, 2014. We believe the current cash position is sufficient to fund our operations into 2018 through several important milestones as detailed below.

2015 Corporate and Clinical Highlights

At the beginning of 2015, we announced our new strategy for accelerated growth focused on prioritizing existing and new pipeline candidates to focus on bio-better products with a clear competitive advantage.

We reported interim results from our phase I/II clinical trial of PRX-102 for the treatment of Fabry disease demonstrating positive efficacy data across all disease parameters and positive safety data with a low level of antibody formation for the 0.2 and 1.0 mg/kg doses. Following a successful end-of-phase II meeting with the FDA, we announced plans to conduct two phase III clinical trials for PRX-102. We submitted a request for a Special Protocol Assessment (SPA) to the FDA, and plan to commence both trials during the first half of 2016.

Data was presented for AIR DNase (PRX-110) at the 38th European Cystic Fibrosis Conference demonstrating that the compound is resistant to actin, a potent inhibitor of DNase that is found in high concentrations in the lungs of cystic fibrosis patients. We are currently in the final dosing stages of our phase I clinical trial for PRX-110, and expect to start a proof of concept study in cystic fibrosis patients around mid year 2016.

We reported positive results from our phase I clinical trial of OPRX-106, an orally-administered antiTNF. The trial demonstrated favorable safety profile and activity in the gut along with activation of regulatory T cells. We expect to initiate a proof of concept clinical trial in mild to moderate ulcerative colitis patients by mid year 2016. If successful, OPRX-106 will be the first ever oral enzyme treatment.

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; 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; 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; 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

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

Source: Protalix BioTherapeutics, Inc.

PROTALIX BIOTHERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share amounts)

	December 31,	
	2014	**2015**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 54,767	$ 76,374
Other assets	2,202	1,667
Inventories	3,451	5,767
Assets of discontinued operation	5,100	2,073
Total current assets	65,520	85,881
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,555	1,628
PROPERTY AND EQUIPMENT, NET	11,282	9,744
Total assets	$ 78,357	$ 97,253
LIABILITIES AND SHAREHOLDERS' EQUITY (NET OF CAPITAL DEFICIENCY)		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 3,836	$ 3,629
Other	6,802	5,534
Deferred revenues	886	504
Liabilities of discontinued operation	52,830	1,568
Total current liabilities	64,354	11,235
LONG TERM LIABILITIES:		
Convertible notes	67,351	67,796
Deferred revenues		744
Liability for employee rights upon retirement	2,253	2,304
Promissory note		4,301
Total long term liabilities	69,604	75,145
Total liabilities	133,958	86,380
COMMITMENTS		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):		
Common Stock, $0.001 par value: Authorized - as of December 31, 2014 and 2015, 150,000,000 shares; issued and outstanding - as of December 31, 2014 and 2015, 93,603,819 shares and 99,800,397 shares, respectively	94	100
Additional paid-in capital	185,633	194,064
Accumulated deficit	(241,328)	(183,291)
Total shareholders' equity (capital deficiency)	(55,601)	10,873
Total liabilities and shareholders' equity (net of capital deficiency)	$ 78,357	$ 97,253

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

	Year ended December 31,		
	2013	**2014**	**2015**
REVENUES	$ 0	$ 3,523	$ 4,364
COST OF REVENUES	0	(630)	(730)
GROSS PROFIT	0	2,893	3,634
RESEARCH AND DEVELOPMENT EXPENSES	(29,225)	(27,352)	(24,889)
Less – grants	3,213	5,128	4,864
RESEARCH AND DEVELOPMENT EXPENSES, NET	(26,012)	(22,224)	(20,025)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(8,051)	(9,228)	(7,279)
OPERATING LOSS	(34,063)	(28,559)	(23,670)
FINANCIAL EXPENSES	(1,065)	(4,935)	(3,735)
FINANCIAL INCOME	391	196	123
FINANCIAL EXPENSES – NET	(674)	(4,739)	(3,612)
LOSS FROM CONTINUING OPERATIONS	(34,737)	(33,298)	(27,282)
Income FROM DISCONTINUED OPERATIONS	6,947	3,355	85,319
NET INCOME (LOSS) FOR THE YEAR	$ (27,790)	$ (29,943)	$ 58,037
NET INCOME (LOSS) PER SHARE OF COMMON STOCK – BASIC AND DILUTED			
Loss from continuing operations	$ (0.38)	$ (0.36)	$ (0.29)
Income from discontinued operations	0.08	0.04	0.90
Net income (loss) per share of common stock	$ (0.30)	$ (0.32)	$ 0.61
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE OF COMMON STOCK, BASIC AND DILUTED	92,368,138	92,891,846	94,922,390