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 12, 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 March 12, 2015, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal year ended December 31, 2014 and providing an update on recent corporate developments. 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 12, 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: March 12, 2015

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

Protalix BioTherapeutics Reports Full Year 2014 Financial Results and Provides Corporate Update

CARMIEL, Israel, March 12, 2015 -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), today reported financial results for the year ended December 31, 2014 and provided an update on recent corporate developments.

Financial Results for the Year Ended December 31, 2014

- Total revenues for the full year ended December 31, 2014 were $13.7 million compared to $10.5 million for the full year ended December 31, 2013.

- Elelyso™ revenues from sales of the product increased 53.6% to $9.1 million for the full year ended December 31, 2014 compared to $5.9 million for the full year ended December 31, 2013. This increase is primarily due to $3.5 million in revenues recorded from sales in Brazil under the supply and technology transfer agreement.

- Protalix's share in the collaboration agreement with Pfizer for the full year ended December 31, 2014 increased to $1.5 million compared to $1.0 million for the full year ended December 31, 2013, despite last quarter's net loss of approximately $750,000, mainly due to one-time charges in connection with launch activities in Canada.

- Elelyso worldwide product sales for the full year ended December 31, 2014 were $25.9 million, an increase of approximately 30%, compared to sales of $20.0 million for the full year ended December 31, 2013.

- Cost of revenues was $9.1 million for the full year ended December 31, 2014 compared to $5.4 million for the full year ended December 31, 2013. Protalix recognized $6.1 million in gross profit for both fiscal years 2014 and 2013. The increase in cost of revenues is mainly attributed to the cost of products sold to Pfizer.

- Selling, general and administrative expenses for the full year ended December 31, 2014 were $9.7 million compared to $8.4 million for the full year ended December 31, 2013.

- Net loss for the full year 2014 was $29.9 million, or $0.32 per share, compared to $27.8 million, or $0.30 per share, for the full year 2013.

- Cash and cash equivalents as of December 31, 2014 were $54.8 million.

Corporate Update and Operation Highlights

- In January 2015, Protalix announced a new strategy for accelerated growth focused on developing products with potentially clinically superior profiles that offer a clear competitive advantage over other products.

- For PRX-102, interim results from the phase I/II clinical trial of Fabry patients demonstrated positive results across all disease parameters. Completion of enrollment in this trial was announced on February 2, 2015. Interim data from the 1mg/kg dose cohort of the trial is expected during the third quarter of 2015, with final results by year end. Protalix expects to launch a phase III pivotal trial, which is planned to be a head-to-head study comparing PRX-102 to a commercially available enzyme replacement therapy for Fabry disease, in early 2016.

- In February 2015, the last Gaucher patient was treated in Protalix's phase IIa clinical trial of oral GCD. An initial analysis of the results demonstrates that oral GCD was safe and well tolerated. Active GCD enzyme was detected in the blood circulation of 10 out of the 17 participants in the trial. In addition, elevated platelet levels were observed in 10 out of the 17 participants in the trial. In 2015, Protalix intends to focus its efforts on reformulating oral GCD in order to prepare a viable solution for further clinical development.

- Protalix is currently reviewing potential indications for its planned oral antiTNF study. This trial is expected to be launched in the second half of this year, enrolling first healthy volunteers and then patients. Results are expected to be released in early 2016.

- Protalix is also currently evaluating clinical sites for its planned AIR DNase trial, which is expected to first enroll healthy volunteers and then cystic fibrosis patients. The trial is being designed to run as a head-to-head study comparing AIR DNase to Pulmozyme. Protalix expects that this trial will be launched in the second half of this year with results released in early 2016.

- In the United States, Elelyso is being prescribed to approximately 30% of newly diagnosed patients and to approximately 25% of all switch patients; however, the total number of patient switches is relatively low.

- Protalix reorganized its scientific advisory board establishing a core team consisting of Roger D. Kornberg, Ph.D., Professor Aaron Ciechanover, M.D., D.Sc., Alexander Levitzki, Ph.D. and Richard Lerner, M.D. Dr. Kornberg and Dr. Ciechanover are both laureates of the Nobel Prize in Chemistry.

“We continue to work closely with Pfizer, the Gaucher community and payors to increase ELELYSO™ market share across all territories. While this growth has been slower than anticipated, the number of patients on drug continues to increase steadily year over year,” said Moshe Manor, Protalix’s President and Chief Executive Officer. “On the clinical development front, we are very excited about the potential of PRX-102 to treat Fabry disease. This sentiment was echoed by the physician community at the WORLD annual meeting last month, where the positive interim results from the first dosing cohort were presented. In 2015, we look forward to announcing additional interim and full results from the PRX-102 phase I/II clinical trial and commencing proof of concept studies for oral antiTNF and AIR DNase.”

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 under our supply and technology transfer; 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: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; 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 BioTherapuetics

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

	December 31,	
	2013	**2014**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 86,398	$ 54,767
Accounts receivable- Trade	2,091	1,884
Other assets	1,457	2,202
Inventories	7,957	6,667
Total current assets	97,903	65,520
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,578	1,555
PROPERTY AND EQUIPMENT, NET	13,711	11,282
DEFERRED CHARGES	141	113
Total assets	$ 113,333	$ 78,470
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,254	$ 3,951
Other	12,073	15,496
Deferred revenues	9,369	6,763
Total current liabilities	26,696	26,210
LONG TERM LIABILITIES:		
Convertible notes	67,048	67,464
Deferred revenues	41,796	37,232
Liability in connection with collaboration operation	2,371	912
Liability for employee rights upon retirement	2,368	2,253
Total long term liabilities	113,583	107,861
Total liabilities	140,279	134,071
COMMITMENTS		
CAPITAL DEFICIENCY:		
Common Stock, $0.001 par value:		
Authorized - as of December 31, 2013 and 2014, 150,000,000 shares; issued and outstanding - as of December 31, 2013 and 2014, 93,551,098 shares and 93,603,819 shares, respectively	93	94
Additional paid-in capital	184,346	185,633
Accumulated deficit	(211,385)	(241,328)
Total capital deficiency	(26,946)	(55,601)
Total liabilities net of capital deficiency	$ 113,333	$ 78,470

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

	Year ended December 31,	
	2013	**2014**
REVENUES	$ 10,479	$ 13,651
COMPANY'S SHARE IN COLLABORATION AGREEMENT	1,034	1,509
COST OF REVENUES	(5,428)	(9,053)
GROSS PROFIT	6,085	6,107
RESEARCH AND DEVELOPMENT EXPENSES	(33,313)	(29,761)
Less – grants and reimbursements	8,497	8,111
RESEARCH AND DEVELOPMENT EXPENSES, NET	(24,816)	(21,650)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(8,385)	(9,661)
OPERATING LOSS	(27,116)	(25,204)
FINANCIAL EXPENSES	(1,065)	(4,935)
FINANCIAL INCOME	391	196
FINANCIAL INCOME (EXPENSES) – NET	(674)	(4,739)
NET LOSS FOR THE YEAR	$ (27,790)	$ (29,943)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.30)	$ (0.32)
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