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 6, 2018

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**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 communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition

On March 6, 2018, Protalix BioTherapeutics, Inc. issued a press release announcing its financial results for the full-year ended December 31, 2017, and providing a corporate update. 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 6, 2018.

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.

Date: March 6, 2018

PROTALIX BIOTHERAPEUTICS, INC.

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

Protalix BioTherapeutics Reports 2017 Full Year Results and Provides Corporate Update

Enrollment in all Fabry Trials is ongoing in over Forty Active Sites

Current Cash is Projected to Fund the Company through Clinical Trial Read-Outs and into 2020

CARMIEL, Israel, March 6, 2018 – GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE American:PLX, TASE:PLX), a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®, today announced its financial results for the full-year ended December 31, 2017 and provided a corporate update.

“This has been an exciting year with a great partnership deal and good progress in all of our clinical programs,” said Moshe Manor, Protalix’s President and Chief Executive Officer. “Looking ahead to 2018, we expect to generate and release more data regarding our clinical trials, and to continue the progress of our programs, both with potential partners and with our current partner, Chiesi Farmaceutici.”

2017 and Recent Clinical and Corporate Highlights

Pegunigalsidase (PRX-102) for Fabry Disease

- The Company has over 40 clinical trial sites actively recruiting patients for three trials, a significant portion of which are located in the United States. The trials are being run by leading opinion leaders in the Fabry disease field.
- The Company expects to finalize enrollment in all three Fabry trials during 2018.
- Pegunigalsidase alfa granted Fast Track designation from the U.S. Food and Drug Administration; the designation is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.
- Pegunigalsidase alfa granted Orphan Drug Designation by the European Commission which qualifies the Company for access to the centralized marketing authorization procedure, including applications for inspections and for protocol assistance. The designation was based on the Company having established medically plausible evidence that pegunigalsidase alfa will provide a significant benefit over existing treatments in the European Union for the treatment of Fabry disease.

Alidornase (PRX-110) for Cystic Fibrosis

- The Cystic Fibrosis Foundation Grant Review is in the final stages of completion.

Oral antiTNF (OPRX-106) for Ulcerative Colitis

- The Company expects to release top-line data this month, with full data planned to be presented in a medical conference later in the year.
- Interim data was positive, with initial signs of efficacy across multiple clinically meaningful endpoints.

Alfataliglicerase for Gaucher Disease

- The Company recognized alfataliglicerase sales of $7.1 million in Brazil for 2017. In addition, the Company shipped approximately $2.6 million worth of the drug during the current quarter.

Full-Year 2017 Financial Results

- The Company recorded total revenues of $19.2 million during the year ended December 31, 2017, compared to $9.2 million for the same period of 2016. The increase resulted from an increase equal to $3.0 million of products sold to Brazil, and $7.0 million of drug substance sold to Pfizer Inc.

- Research and development expenses for the year ended December 31, 2017, were $28.8 million, compared to $24.6 million for the same period in 2016. Selling, general and administrative expenses for the year ended December 31, 2017 were $11.5 million, compared to $9.4 million incurred during the same period in 2016.

- Operating loss for the year ended December 31, 2017 was $36.4 million compared to $33.2 million for the year ended December 31, 2016.

- For the year ended December 31, 2017, the Company reported a net loss of $47.2 million, excluding a one-time, non-cash net charge of $38.1 million in connection with the remeasurement of a derivative, or $0.36 per share, basic and diluted, compared to a net loss of $29.4 million, or $0.29 per share, basic and diluted, for the same period of 2016.

- On December 31, 2017, the Company had $51.2 million of cash and cash equivalents, compared to $63.3 million at December 31, 2016, which is currently projected to fund operations into 2020. As of December 31, 2017, the Company had outstanding $5.9 million of its 4.5% convertible notes due September 2018 and $59.1 million of its 7.5% senior secured convertible notes due November 2021.

Conference Call and Webcast Information

The Company will host a conference call on Tuesday, March 6, 2018, at 8:30 am ET to review the clinical, corporate and financial highlights.

To participate in the conference call, please dial the following numbers prior to the start of the call: United States: +1-844-358-6760; International: +1-478-219-0004. Conference ID number 2636229.

The conference call will also be broadcast live and available for replay for two weeks on the Company's website, www.protalix.com, in the Events Calendar of the Investors section. Please access the Company's website at least 15 minutes ahead of the conference to register, download, and install any necessary audio software.

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: pegunigalsidase alfa, 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; alidornase alfa for the treatment of Cystic Fibrosis; and others. Protalix has entered into an ex-United States partnership with Chiesi Farmaceutici S.p.A. for the development and commercialization of pegunigalsidase alfa. Protalix maintains full rights to pegunigalsidase alfa in the United States.

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 “expect,” “anticipate, “believe,” “estimate,” “project,” “plan,” “should” 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 superiority, 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 ultimate purchase by Fundação Oswaldo Cruz of alfataliglicerase pursuant to the stated purchase intentions of the Brazilian Ministry of Health of the stated amounts, if at all; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase generally; risks related to our commercialization efforts for alfataliglicerase in Brazil; 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 amount and sufficiency of our cash and cash equivalents; risks related to the amount of our future revenues, operations and expenditures; risks related to our ability to maintain and manage our relationship with Chiesi Farmaceutici and any other collaborator, distributor or partner; the risk that despite the FDA’s grant of fast track designation for pegunigalsidase alfa for the treatment of Fabry disease, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA’s ability to withdraw the fast track designation at any time; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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 press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Investor Contact

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Source: Protalix BioTherapeutics, Inc.

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

	December 31,	
	2016	**2017**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 63,281	$ 51,163
Accounts receivable – Trade	693	1,721
Other assets	2,648	1,934
Inventories	5,245	7,833
Total current assets	71,867	62,651
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,677	1,887
PROPERTY AND EQUIPMENT, NET	8,703	7,676
Total assets	$ 82,247	$ 72,214
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,007	$ 7,521
Other	7,496	9,310
Convertible notes	53,872	5,921
Deferred revenues	837	
Total current liabilities	66,212	22,752
LONG TERM LIABILITIES:		
Convertible notes	19,343	46,267
Deferred revenues		26,851
Liability for employee rights upon retirement	2,348	2,586
Other long term liabilities	4,301	5,051
Total long term liabilities	25,992	80,755
Total liabilities	92,204	103,507
COMMITMENTS (Note 6)		
CAPITAL DEFICIENCY:		
Common Stock, $0.001 par value: Authorized – as of December 31, 2016 and 2017, 250,000,000 shares; issued and outstanding, respectively – as of December 31, 2016 and 2017, 124,134,085 shares and 143,728,797 shares, respectively	124	144
Additional paid-in capital	202,575	266,495
Accumulated deficit	(212,656)	(297,932)
Total capital deficiency	(9,957)	(31,293)
Total liabilities net of capital deficiency	$ 82,247	$ 72,214

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

	Year ended December 31,		
	2015	**2016**	**2017**
REVENUES	$ 4,364	$ 9,199	$ 19,242
COST OF REVENUES	(730)	(8,398)	(15,231)
GROSS PROFIT	3,634	801	4,011
RESEARCH AND DEVELOPMENT EXPENSES	(24,889)	(30,412)	(32,170)
Less – grants	4,864	5,804	3,336
RESEARCH AND DEVELOPMENT EXPENSES, NET	(20,025)	(24,608)	(28,834)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES	(7,279)	(9,356)	(11,530)
OPERATING LOSS	(23,670)	(33,163)	(36,353)
FINANCIAL EXPENSES	(3,735)	(4,192)	(9,725)
FINANCIAL INCOME	123	589	188
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE		(6,473)	(38,061)
(LOSS) GAIN ON EXTINGUISHMENT OF CONVERTIBLE NOTES		14,063	(1,325)
FINANCIAL (EXPENSES) INCOME – NET	(3,612)	3,987	(48,923)
LOSS FROM CONTINUING OPERATIONS	(27,282)	(29,176)	(85,276)
(LOSS) INCOME FROM DISCONTINUED OPERATIONS	85,319	(189)	
NET (LOSS) INCOME FOR THE YEAR	$ 58,037	$ (29,365)	$ (85,276)
NET (LOSS) INCOME PER SHARE OF COMMON STOCK – BASIC AND DILUTED			
Loss from continuing operations	$ (0.29)	$ (0.29)	$ (0.65)
Income from discontinued operations	0.90	(0.00)	
Net (loss) income per share of common stock	$ 0.61	$ (0.29)	$ (0.65)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE OF COMMON STOCK, BASIC AND DILUTED	94,922,390	101,387,704	131,085,958