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): May 10, 2017

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**	**20100**
(Address of principal executive offices)	**(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 May 10, 2017, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2017. 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 May 10, 2017.

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: May 10, 2017

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

Exhibit 99.1

Protalix BioTherapeutics Reports 2017 First Quarter Results and Provides Corporate Update

Positive Results from Phase II Trial in CF Program with Number of Potential Strategic Alternatives for Further Development

First Ever Once Monthly Dosing Trial in Fabry Patients to Commence Next Quarter

Continued Progress in the Commercialization of alfataliglicerase in Brazil

CARMIEL, Israel, May 10, 2017 -- GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE MKT: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 three months ended March 31, 2017 and provided a corporate update.

"This quarter we remained focused on driving our lead clinical asset pegunigalsidase alfa through clinical development including FDA clearance of our IND for the first ever once monthly dose of pegunigalsidase alfa. This will further differentiate pegunigalsidase and its potential superiority to currently available therapies. We also announced very strong, positive results for alidornase alfa from our Phase II study in Cystic Fibrosis," said Moshe Manor, President and CEO of Protalix. "Additionally, in the first quarter we recorded increased revenue from sales of alfataliglicerase in Brazil and we anticipate revenues will further increase significantly throughout the year."

2017 First Quarter and Recent Clinical and Corporate Highlights

Pegunigalsidase alfa (PRX-102) for Fabry Disease

- Received FDA IND clearance to initiate a trial evaluating once monthly dosing of 2mg/kg of PRX-102 in Fabry patients. This is a first in class study that is supported by pegunigalsidase alfa superior circulatory half-life when compared to approved enzyme replacement therapies for Fabry disease.

- Presented the phase I/II clinical trial results in an official satellite of the World Congress of Nephrology, titled, *The Fifth Update on Fabry Nephropathy*.

Alidornase alfa (PRX-110) for Cystic Fibrosis

- Reported positive results from our phase II clinical trial in April 2017. Final analysis of the data demonstrated a mean absolute increase in the percent predicted forced expiratory volume in one second (ppFEV1) of 3.4 points from baseline and a mean absolute increase in ppFEV1 of 3.3 points (previously reported 2.8) from last inhalation of Pulmozyme®.

- Data from the study was accepted as an oral presentation at the 40th European Cystic Fibrosis Conference and will be presented in June 2017.

- The Cystic Fibrosis Foundation invited Protalix to submit a Letter of Intent to its Therapeutics Development Award program, following their initial review of our phase II clinical trial final results. Protalix welcomes the opportunity and also intends to seek the foundation's guidance and advice for the further development of alidornase alfa.

- In parallel, Protalix is in active discussions regarding potential collaboration with certain potential partners, our advisory board and regulatory consultant regarding our clinical strategy for alidornase alfa.

Oral anti-TNF (OPRX-106) for Ulcerative Colitis

- Enrollment in a phase II clinical trial is currently ongoing in number of sites globally. Full results are expected around year-end.

Alfataliglicerase for Gaucher Disease

- On March 22, 2017, received a formal purchase order (PO) of $24.3 million of drug product from Fundação Oswaldo Cruz (Fiocruz), an arm of the Brazilian Ministry of Health formalizing the letter of intent received and announced earlier in January 2017.

- On May 6, Fiocruz, with participation of senior Ministry of Health officials and Protalix management held a conference "Mude Perspectivas. Gaucher" ("Change Perspectives in Gaucher") in Rio de Janeiro hosting over 60 leading Gaucher treating physicians from across Brazil . Key officials from the Brazilian Ministry of Health stressed their commitment to the Gaucher community and announced the adoption of the CONITEC, National Committee for Technology Incorporation, recommendation to treat all Gaucher patients aged four and older with alfataliglicerase (the Protocol). At the conference, CONITEC presented that the Protocol was approved during its 55th meeting. After the Health Minister's signature, the protocol will be published in the Gazette.

- The Company has increased its manufacturing activities significantly, nearing full capacity, to meet the $24.3 million of product demand and in anticipation for the expected future increased orders.

- The first shipment of approximately $6 million of alfataliglicerase from the $24.3M request, is currently being prepared for shipment around June with additional shipments scheduled for September and December for the balance of the PO, as planned.

Three Months ended March 31, 2017 Financial Results

- Protalix reported a net loss of $8.3 million, or $0.07 per share, basic and diluted, excluding one time non cash net charges of $50.9 million in connection with the remeasurement of a derivative which will be reversed in its entirety into the Company's income statement and shareholder equity section in the next quarter, compared to a net loss of $8.6 million, or $0.09 per share, basic and diluted, for 2016 from continuing operations.

- Protalix recorded total revenues of $2.9 million, compared to $679,000 during the same period of 2016. The increase is attributed mainly to increased sales of drug product to Brazil totaling $1.2 million and an increase of $900,000 of drug substance sold to Pfizer Inc.

- Research and development expenses were $4.6 million, compared to $6.0 million for the same period in 2016. Selling, general and administrative expenses were $2.5 million, compared to $2.0 incurred during the same period of 2016. The increase is mainly attributable to increased activities in Brazil.

- On March 31, 2017 Protalix had $48.0 million of cash and cash equivalents, which is currently projected to fund operations into 2019.

Conference Call and Webcast Information

The Company will host a conference call on Wednesday, May 10, 2017, 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 17333001.

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.

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: 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; 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 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; 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; 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)
(Unaudited)

	March 31, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 48,017	$ 63,281
Accounts receivable – Trade	2,737	693
Other assets	3,484	2,321
Inventories	7,100	5,245
Assets of discontinued operation	205	327
Total current assets	61,543	71,867
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,837	1,677
PROPERTY AND EQUIPMENT, NET	8,472	8,703
Total assets	$ 71,852	$ 82,247
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 5,999	$ 4,007
Other	12,365	7,496
Convertible notes		53,872
Deferred revenues	1,925	837
Total current liabilities	20,289	66,212
LONG TERM LIABILITIES:		
Convertible notes	113,204	19,343
Liability for employee rights upon retirement	2,528	2,348
Promissory note	4,301	4,301
Total long term liabilities	120,033	25,992
Total liabilities	140,322	92,204
COMMITMENTS		
CAPITAL DEFICIENCY	(68,470)	(9,957)
Total liabilities net of capital deficiency	$ 71,852	$ 82,247

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

	Three Months Ended	
	March 31, 2017	**March 31, 2016**
REVENUES	$ 2,889	$ 679
COST OF REVENUES	(2,088)	(523)
GROSS PROFIT	801	156
RESEARCH AND DEVELOPMENT EXPENSES (1)	(5,967)	(7,334)
Less – grants	1,338	1,309
RESEARCH AND DEVELOPMENT EXPENSES, NET	(4,629)	(6,025)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(2,537)	(1,995)
OPERATING LOSS	(6,365)	(7,864)
FINANCIAL EXPENSES	(2,087)	(904)
FINANCIAL INCOME	1,625	242
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE	(52,321)	
FINANCIAL EXPENSES, NET	(52,783)	(662)
LOSS FROM CONTINUING OPERATIONS	(59,148)	(8,526)
LOSS FROM DISCONTINUED OPERATIONS		(72)
NET LOSS FOR THE PERIOD	$ (59,148)	$ (8,598)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED		
Loss from continuing operations	$ (0.48)	$ (0.09)
Loss from discontinued operations		(0.00)
Net loss per share of common stock	$ (0.48)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	124,467,602	99,715,625
(1) Includes share-based compensation	65	238
(2) Includes share-based compensation	53	137