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 9, 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**	**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 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 May 9, 2018, Protalix BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2018. 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 9, 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: May 9, 2018

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports 2018 First Quarter Results and Provides Corporate Update

CARMIEL, Israel, May 9, 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 three months ended March 31, 2018 and provided a corporate update.

"We continue to execute against our upcoming milestones, including the completion of enrollment in our phase III clinical trials of PRX-102 and exploring potential partnering opportunities for our clinical assets," said Moshe Manor, Protalix's President and Chief Executive Officer. "We reported positive results for OPRX-106 in the first quarter of this year, which not only demonstrate the drug's potential in the treatment of ulcerative colitis, but also highlight the potential of our ProCellEx platform technology to deliver biologics orally."

2018 First Quarter and Recent Clinical Highlights

- Continued enrollment in the three Phase III trials, the BALANCE, BRIDGE and BRIGHT studies, for pegunigalsidase alfa (PRX-102) for the treatment of Fabry disease at nearly 50 clinical trial sites worldwide.
- Testing of blood samples from certain patients screened for the BALANCE study were analyzed for anti-drug antibody (ADA) presence and neutralizing activity, and the cross-reactivity and inhibition of such antibodies to PRX-102. A description of the data from the analysis has been accepted as a poster presentation scheduled on May 25, 2018 at the 55th ERA-EDTA Congress (European Renal Association – European Dialysis and Transplant Association) being held in Copenhagen, Denmark, May 24-27, 2018.
- Reported positive top-line clinical results for the Company's OPRX-106 phase IIa clinical trial in ulcerative colitis patients.
- Oral presentation detailing the results from the Company's phase IIa clinical trial of OPRX-106 for the treatment of ulcerative colitis accepted for the Digestive Disease Week® (DDW) 2018 Annual Meeting in Washington, D.C., June 2-5, 2018.
- The presentation at the DDW will include new clinical data and detailed per patient results further supporting the consistent effect in patients.

Financial Results for Three Months ended March 31, 2018

- The Company reported a net loss of $9.4 million, or $0.06 per share, basic and diluted for the three-month period ended March 31, 2018 compared to a net loss of $8.4 million, or $0.07 per share, basic and diluted, excluding a one-time, non-cash charge of $52.3 million in connection with the remeasurement of a derivative, for the three-month period ended March 31, 2017.
- The Company recorded total revenues of $4.6 million for the three-month period ended March 31, 2018, compared to $2.9 million for the same period of 2017. The increase is attributed mainly to increased sales of alfataliglicerase in Brazil.

- Research and development expenses were $7.3 million for the three-month period ended March 31, 2018, compared to $6.0 million for the same period of 2017. The increase is mainly due to the advanced stages of the Company's clinical trials of its drug candidates.

- Selling, general and administrative expenses were $2.5 million for the three-month period ended March 31, 2018, and March 31, 2017.

- As of March 31, 2018, the Company had $41.3 million of cash and cash equivalents.

Conference Call and Webcast Information

The Company will host a conference call on Wednesday, May 9, 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 8190507.

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

	March 31, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,319	$ 51,163
Accounts receivable – Trade	4,756	1,721
Other assets	2,594	1,934
Inventories	7,019	7,833
Total current assets	$ 55,688	$ 62,651
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,798	1,887
PROPERTY AND EQUIPMENT, NET	7,311	7,676
Total assets	$ 64,797	$ 72,214
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,872	$ 7,521
Other	10,697	9,310
Convertible notes	5,930	5,921
Total current liabilities	$ 21,499	$ 22,752
LONG TERM LIABILITIES:		
Convertible notes	46,108	46,267
Deferred revenues	29,030	26,851
Liability for employee rights upon retirement	2,427	2,586
Other long term liabilities	5,172	5,051
Total long term liabilities	$ 82,737	$ 80,755
Total liabilities	$ 104,236	$ 103,507
COMMITMENTS		
CAPITAL DEFICIENCY	(39,439)	(31,293)
Total liabilities net of capital deficiency	$ 64,797	$ 72,214

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, 2018	**March 31, 2017**
REVENUES	$ 4,553	$ 2,889
COST OF REVENUES	(2,924)	(2,088)
GROSS PROFIT	1,629	801
RESEARCH AND DEVELOPMENT EXPENSES (1)	(7,286)	(5,967)
Less – grants	843	1,338
RESEARCH AND DEVELOPMENT EXPENSES, NET	(6,443)	(4,629)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(2,498)	(2,537)
OPERATING LOSS	(7,312)	(6,365)
FINANCIAL EXPENSES	(2,220)	(2,087)
FINANCIAL INCOME	132	1,625
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE		(52,321)
FINANCIAL (EXPENSES) INCOME, NET	(2,088)	(52,783)
LOSS FOR THE PERIOD	(9,400)	(59,148)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED	$ (0.06)	$ (0.48)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	145,305,982	124,467,602
(1) Includes share-based compensation	42	65
(2) Includes share-based compensation	20	53