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): November 8, 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** **(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 November 8, 2017, Protalix BioTherapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 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 November 8, 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.

Date: November 8, 2017

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports 2017 Third Quarter Results and Provides Corporate Update

Collaboration Agreement with Chiesi Farmaceutici Further Validates Fabry Program and Significantly Improves Financial Position

Sufficient Capital Resources to Fund Operations into 2020

Balance Sheet Further Strengthened by the Reduction of Debt via Conversion of the Entire $8.55 Million of 2022 Notes

CARMIEL, Israel, November 8, 2017 -- 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 nine months ended September 30, 2017 and provided a corporate update.

"I am excited about the progress we made recently," said Moshe Manor, Protalix's President and Chief Executive Officer. "We are no longer facing any debt issue or financing overhang. Moreover, with the recent strategic collaboration with Chiesi, not only did we secure a strong, experienced clinical and commercial partner, but we also meaningfully increased our capital resources, providing us with sufficient cash into 2020, irrespective of any milestone payments we are entitled to from Chiesi, increased revenues or from future partnerships. In addition, on the strategic front, we now have three novel and clinically differentiated product candidates in the clinic with potentially superior efficacy which provides us multiple shots at goal to realize significant value for our stockholders."

Third Quarter and Recent Clinical Highlights

Pegunigalsidase alfa (PRX-102) for Fabry Disease

- Protalix entered into an EX-US collaboration agreement with Chiesi Farmaceutici S.p.A., or Chiesi, for pegunigalsidase alfa, or PRX-102. Under the terms of the agreement, Protalix is entitled to an upfront payment of $25 million from Chiesi, up to $25 million to cover development costs for pegunigalsidase alfa, subject to a maximum of $10 million per year, and up to an additional $320 million in regulatory and commercial milestone payments. Additionally, Protalix is entitled to tiered payments of 15% to 35% of Chiesi's net sales.

- Patient enrollment in the Company's phase III clinical trials, referred to as the Balance, Bridge and Bright studies, is on-going.

Alidornase alfa (PRX-110) for Cystic Fibrosis

- Protalix applied for a financial grant from the Cystic Fibrosis Foundation to support the clinical development of alidornase alfa.

- A poster titled “Development of Novel Actin Inhibition Resistant DNase I Enzyme - alidornase alfa - for the Treatment of Cystic Fibrosis" was presented at the North American Cystic Fibrosis Conference held in November 2017.

Oral antiTNF (OPRX-106) for Ulcerative Colitis

- The final patients needed to complete enrollment in the Company’s phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis are in the screening process. The Company remains on track to complete enrollment during the fourth quarter and report top-line results in early 2018.

Alfataliglicerase for Gaucher Disease

- Shipment of approximately $3.0 million of alfataliglicerase was completed this quarter for a total of $6.6 million for the nine months ended September 30, 2017.

- According to the purchase order received by the Company, additional shipments are scheduled to be made during fourth quarter of 2017, and into 2018.

Financial Results for Nine Months ended September 30, 2017

- The Company reported a net loss of $32.1 million, or $0.25 per share, basic and diluted, for the nine-month period ended September 30, 2017, excluding a one-time, non-cash net charge of $38.1 million in connection with the remeasurement of a derivative, compared to a net loss of $26.7 million, or $0.27 per share, basic and diluted, for the same period of 2016.

- The Company recorded total revenues of $16.8 million for the nine-month period ended September 30, 2017, compared to $7.1 million during the same period of 2016. The increase is primarily the result of increased sales of drug product to Brazil of $6.6 million in the nine months ended September 30, 2017, compared to $2.7 million in the same period of 2016, and the sale of drug substance to Pfizer Inc.

- Research and development expenses, net were $19.8 million for the nine-month period ended September 30, 2017, compared to $18.9 million for the same period of 2016. Selling, general and administrative expenses were $8.2 million for the nine-month period ended September 30, 2017, compared to $6.2 million incurred during the same period of 2016. The increases are primarily attributed to increased activities in three ongoing clinical trials and selling in Brazil.

- During the nine-month period ended September 30, 2017 and during October, note holders converted the entire $8.55 million in aggregate principal amount of the Company’s 4.50% convertible notes due 2022.

- As of today, the Company’s outstanding convertible notes include 4.50% convertible notes due September 2018 with an aggregate principal amount of $5.9 million and senior secured 7.50% convertible notes due November 2021 with an aggregate principal amount of $61.9 million.

- On September 30, 2017, the Company had $33.4 million of cash and cash equivalents. With the Company's current cash, plus the additional $25 million upfront payment due from Chiesi, and without giving effect to any milestone payment we are entitled to from Chiesi, anticipated increase in revenue run rate or any additional potential partnerships, the Company has sufficient resources to fund operations into 2020.

Conference Call and Webcast Information

The Company will host a conference call on Wednesday, November 8, 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: (844) 358-6760; International: (478) 219-0004. Conference ID number 6767278.

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: 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 our ability to maintain and manage our relationship with Chiesi Farmaceutici and any other collaborator, distributor or partner; 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)

	September 30, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 33,482	$ 63,281
Accounts receivable – Trade	7,292	693
Other assets	2,689	2,321
Inventories	7,479	5,245
Assets of discontinued operation	211	327
Total current assets	$ 51,153	$ 71,867
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,919	1,677
PROPERTY AND EQUIPMENT, NET	7,986	8,703
Total assets	$ 61,058	$ 82,247
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 8,691	$ 4,007
Other	11,989	7,496
Convertible notes	5,911	53,872
Deferred revenues		837
Total current liabilities	$ 26,591	$ 66,212
LONG TERM LIABILITIES:		
Convertible notes	53,625	19,343
Liability for employee rights upon retirement	2,612	2,348
Promissory note	4,301	4,301
Total long term liabilities	$ 60,538	$ 25,992
Total liabilities	$ 87,129	$ 92,204
COMMITMENTS		
CAPITAL DEFICIENCY	(26,071)	(9,957)
Total liabilities net of capital deficiency	$ 61,058	$ 82,247

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

	Nine Months Ended		Three Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
REVENUES	$ 16,773	$ 7,118	$ 7,526	$ 4,670
COST OF REVENUES	(13,677)	(6,446)	(6,066)	(4,248)
GROSS PROFIT	3,096	672	1,460	422
RESEARCH AND DEVELOPMENT EXPENSES (1)	(22,389)	(23,700)	(7,118)	(6,353)
Less – grants	2,545	4,800	729	1,297
RESEARCH AND DEVELOPMENT EXPENSES, NET	(19,844)	(18,900)	(6,389)	(5,056)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(8,187)	(6,215)	(2,836)	(2,014)
OPERATING LOSS	(24,935)	(24,443)	(7,765)	(6,648)
FINANCIAL EXPENSES	(8,809)	(2,715)	(3,680)	(910)
FINANCIAL INCOME	1,670	606	8	268
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE	(38,061)			
FINANCIAL EXPENSES, NET	(45,200)	(2,109)	(3,672)	(642)
LOSS FROM CONTINUING OPERATIONS	(70,135)	(26,552)	(11,437)	(7,290)
LOSS FROM DISCONTINUED OPERATIONS	-	(189)	-	-
NET LOSS FOR THE PERIOD	$ (70,135)	$ (26,741)	$ (11,437)	$ (7,290)
NET LOSS PER SHARE OF COMMON STOCK – BASIC AND DILUTED				
Loss from continuing operations	(0.55)	(0.27)	(0.09)	(0.07)
Loss from discontinued operations		(0.00)		
Net loss per share of common stock	$ (0.55)	$ (0.27)	$ (0.09)	$ (0.07)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE-BASIC AND DILUTED	128,223,722	99,766,245	132,549,001	99,821,970
(1) Includes share-based compensation	$ 163	$ 448	$ 43	$ 82
(2) Includes share-based compensation	$ 128	$ 317	$ 32	$ 81