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 7, 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 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))

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 7, 2018, Protalix BioTherapeutics, Inc. issued a press release announcing its financial results for the period ended September 30, 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 November 7, 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: November 7, 2018

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Reports 2018 Third Quarter Results and Provides Corporate Update

CARMIEL, Israel, November 7, 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 and nine months ended September 30, 2018, and provided a corporate update.

“In the third quarter we achieved two important milestone events for pegunigalsidase alfa, or PRX-102, our differentiated enzyme replacement therapy in development for the treatment of Fabry disease. First, we expanded our partnership with Chiesi Farmaceutici S.p.A. to include exclusive rights to commercialize and develop PRX-102 in the United States, which significantly strengthened our financial position. Second, we reported positive preliminary results from our BRIDGE study on key kidney function,” commented Moshe Manor, Protalix’s President and Chief Executive Officer. “Based on the promising preliminary BRIDGE study results, and taking into account the newly issued guidance from the U.S. Food and Drug Administration (FDA), we plan to engage with the FDA during the first half of 2019 to discuss the most optimal regulatory path forward for PRX-102. While we continue to enroll patients in all of our currently ongoing Fabry disease studies, we believe that with over 110 Fabry patients enrolled across the studies included in our PRX-102 clinical program to date, we have a sufficient number of patients for expedited review, including filing an application for accelerated approval,” continued Mr. Manor.

2018 Third Quarter Highlights

- Presented preliminary positive data from the BRIDGE study showing Improvement in kidney function in patients switched from agalsidase alfa (Replagal®) to pegunigalsidase alfa and further showing the reversal of a deterioration trend in kidney function to an improvement trend when switched.

- Expanded partnership with Chiesi Farmaceutici S.p.A., or Chiesi, to include U.S. rights for the development and commercialization of PRX-102. Terms of the agreement included an up-front payment of $25 million, up to $20 million in development costs and tiered royalties ranging from 15-40% of net sales.

- Expanded our Board of Directors with the addition of Mr. David Granot as an independent director.

- Continued exploring the potential for partnership opportunities mainly for OPRX-106, and for PRX-110. In parallel, the Company is exploring the option of conducting a controlled phase IIb study of OPRX-106 for the treatment of ulcerative colitis in order to maximize the value of this asset in a manner that will best serve the stockholders’ interest.

Financial Results for the Nine Months ended September 30, 2018

- The Company reported a net loss of $36.2 million, or $0.25 per share, basic and diluted for the nine-month period ended September 30, 2018 compared to a net loss of $32.1 million, or $0.25 per share, basic and diluted for the same period of 2017 excluding remeasurement of a derivative.

- The Company recorded total revenues of $7.2 million for the nine-month period ended September 30, 2018, compared to $16.8 million for the same period of 2017. The decrease resulted primarily from decreased shipments of alfataliglicerase to Brazil despite the increase in the number of patients treated with alfataliglicerase, and decreased sales of drug substance to Pfizer.

- The $25.0 million in proceeds received from Chiesi during the three-month period ended September 30, 2018 as an upfront payment were not recorded as revenues, and were deferred according to the revenue recognition rules of U.S. generally accepted accounting principles. Such proceeds should be recorded upon the commencement of commercial manufacturing. The same accounting treatment was applied to the $25.0 million upfront payment received by the Company in the fourth quarter of 2017, and the $11.8 million of research and development reimbursement payments the Company has received from Chiesi to date.

- Research and development expenses were $23.8 million for the nine-month period ended September 30, 2018, compared to $19.8 million for the same period of 2017.

- Selling, general and administrative expenses were $7.3 million for the nine-month period ended September 30, 2018 compared to $8.2 million for the same period of 2017.

- As of September 30, 2018, the Company had $41.9 million of cash and cash equivalents. With the expected decrease in cash consumption resulting primarily from the Company's U.S. license transaction with Chiesi, the Company expects the cash balance to fund the Company through significant regulatory achievements of PRX-102.

Conference Call and Webcast Information

The Company will host a conference call on Wednesday, November 7, 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 8567317.

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 partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

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: risks that the FDA will not accept an application for accelerated approval of PRX-102 with the data generated to date or will request additional data or other conditions of our submission of any application for accelerated approval of PRX-102; 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 our ability to maintain and manage our relationship with Chiesi Farmaceutici and any other collaborator, distributor or partner; 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; 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; 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

Marcy Nanus
Solebury Trout
646-378-2927
mnanus@soleburytrout.com

Source: Protalix BioTherapeutics, Inc.

PROTALIX BIOTHERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	September 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 41,868	$ 51,163
Accounts receivable – Trade	4,894	1,721
Other assets	2,619	1,934
Inventories	7,959	7,833
Total current assets	$ 57,340	$ 62,651
DEFERRED ASSET	$ 1,450	
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,779	1,887
PROPERTY AND EQUIPMENT, NET	6,628	7,676
Total assets	$ 67,197	$ 72,214
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 4,388	$ 7,521
Other	10,163	9,310
Convertible notes		5,921
Total current liabilities	$ 14,551	$ 22,752
LONG TERM LIABILITIES:		
Convertible notes	47,320	46,267
Deferred revenues	61,780	26,851
Liability for employee rights upon retirement	2,386	2,586
Other long term liabilities	6,154	5,051
Total long term liabilities	$ 117,640	$ 80,755
Total liabilities	$ 132,191	$ 103,507
COMMITMENTS		
CAPITAL DEFICIENCY	(64,994)	(31,293)
Total liabilities net of capital deficiency	$ 67,197	$ 72,214

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, 2018	September 30, 2017	September 30, 2018	September 30, 2017
REVENUES	$ 7,222	$ 16,773	$ 663	$ 7,526
COST OF REVENUES	(7,024)	(13,677)	(1,917)	(6,066)
GROSS PROFIT (LOSS)	198	3,096	(1,254)	1,460
RESEARCH AND DEVELOPMENT EXPENSES (1)	(25,565)	(22,389)	(10,803)	(7,118)
LESS – GRANTS	1,810	2,545	732	729
RESEARCH AND DEVELOPMENT EXPENSES, NET	(23,755)	(19,844)	(10,071)	(6,389)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(7,294)	(8,187)	(2,638)	(2,836)
OPERATING LOSS	(30,851)	(24,935)	(13,963)	(7,765)
FINANCIAL EXPENSES	(5,824)	(8,809)	(1,811)	(3,680)
FINANCIAL INCOME	437	1,670	230	8
LOSS FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE		(38,061)		
FINANCIAL EXPENSES, NET	(5,387)	(45,200)	(1,581)	(3,672)
NET LOSS FOR THE PERIOD	(36,238)	(70,135)	(15,544)	(11,437)
NET LOSS PER SHARE OF COMMON STOCK BASIC AND DILUTED	$ (0.25)	$ (0.55)	$ (0.10)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING LOSS PER SHARE – BASIC AND DILUTED	146,752,355	128,223,722	148,187,513	132,549,001
(1) Includes share-based compensation	$ 54	$ 163	$ 14	$ 43
(2) Includes share-based compensation	$ 42	$ 128	$ 8	$ 32