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): August 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** **(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 August 9, 2018, Protalix BioTherapeutics, Inc. issued a press release announcing its financial results for the period ended June 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 August 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: August 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 Second Quarter Results and Provides Corporate Update

CARMIEL, Israel, August 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 six-month period ended June 30, 2018 and provided a corporate update.

"This has been a fantastic quarter for the company highlighted by the expansion of our partnership with Chiesi that resulted from the strong relationship developed over the past months," commented Moshe Manor, Protalix's President and Chief Executive Officer. "Additionally, we believe that the recent draft guidelines from the U.S. Food and Drug Administration, or the FDA, released in July regarding enzyme replacement therapies could significantly benefit the regulatory path forward for PRX-102."

2018 Second Quarter and Recent Clinical Highlights

- Expanded partnership with Chiesi Farmaceutici S.p.A., or Chiesi, to include exclusive U.S. rights for the development and commercialization of PRX-102. Terms of the agreement include an up-front payment of $25 million, up to $20 million in development costs, up to $760 million, in the aggregate, in regulatory and commercial milestone payments and tiered royalties ranging from 15 to 40%.
- In July, the FDA issued a draft guideline "Slowly Progressive, Low-Prevalence Rare Diseases with Substrate Deposition that Results from Single Enzyme Defects: Providing Evidence of Effectiveness for Replacement or Corrective Therapies". The draft guideline recognizes the challenges in achieving clinical evidence in rare, slow progressing diseases and provides additional preclinical and clinical results that may be acceptable to the FDA in its consideration for accelerated approval. The Company is reviewing the draft guidelines to determine how they might apply to the Company's Fabry clinical development program.
- With the additional cash from Chiesi, the Company is funded through read-outs of all clinical trials of PRX-102.
- Presented data at the Digestive Disease Week® (DDW) 2018 Annual Meeting on OPRX-106, which showed mucosal improvement in 61% of patients, mucosal healing in 33% of patients and clinical responses in 67% of patients.
- Exchanged 4.50% convertible notes for a combination of shares and cash, and effectively discharged the remainder of the 4.50% notes.

Financial Results for the Six Months ended June 30, 2018

- The Company reported a net loss of $20.7 million, or $0.14 per share, basic and diluted for the six-month period ended June 30, 2018 compared to a net loss of $20.6 million, or $0.16 per share, basic and diluted, excluding a one-time, non-cash net charge of $38.1 million in connection with the remeasurement of a derivative, for the same period of 2017.
- The Company recorded total revenues of $6.6 million for the six-month period ended June 30, 2018, compared to $9.2 million for the same period of 2017. The decrease is attributed mainly to lower sales of drug substance to Pfizer Inc. and of alfataliglicerase in Brazil.
- Research and development expenses were $14.8 million for the six-month period ended June 30, 2018, compared to $15.3 million for the same period of 2017. Chiesi's participation in the clinical trials of PRX-102 for the treatment of Fabry disease in the amount of $5.0 million was recorded as deferred revenues and not as a deduction from the research and development expenses.
- Selling, general and administrative expenses were $4.7 million for the six-month period ended June 30, 2018 compared to $5.4 million for the same period of 2017.
- As of June 30, 2018, the Company had $28.3 million of cash and cash equivalents.
- Pro forma cash balance for June 30, 2018 to include the upfront from the exclusive license signed with Chiesi for the rights to PRX-102 in the United States is $53.3 million.

Conference Call and Webcast Information

The Company will host a conference call on Thursday, August 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 9488046.

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: 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 amount and sufficiency of our cash and cash equivalents; 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 Group
646-378-2927
mnanus@troutgroup.com

Source: Protalix BioTherapeutics, Inc.

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

	June 30, 2018	December 31, 2017
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 28,327	$ 51,163
Accounts receivable – Trade	5,248	1,721
Other assets	2,499	1,934
Inventories	6,978	7,833
Total current assets	$ 43,052	$ 62,651
FUNDS IN RESPECT OF EMPLOYEE RIGHTS UPON RETIREMENT	1,729	1,887
PROPERTY AND EQUIPMENT, NET	6,940	7,676
Total assets	$ 51,721	$ 72,214
LIABILITIES NET OF CAPITAL DEFICIENCY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	$ 6,001	$ 7,521
Other	9,071	9,310
Convertible notes		5,921
Total current liabilities	$ 15,072	$ 22,752
LONG TERM LIABILITIES:		
Convertible notes	46,742	46,267
Deferred revenues	31,885	26,851
Liability for employee rights upon retirement	2,335	2,586
Other long term liabilities	5,258	5,051
Total long term liabilities	$ 86,220	$ 80,755
Total liabilities	$ 101,292	$ 103,507
COMMITMENTS		
CAPITAL DEFICIENCY	(49,571)	(31,293)
Total liabilities net of capital deficiency	$ 51,721	$ 72,214

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

	Six Months Ended		Three Months Ended	
	June 30, 2018	June 30, 2017	June 30, 2018	June 30, 2017
REVENUES	$ 6,559	$ 9,247	$ 2,006	$ 6,358
COST OF REVENUES	(5,107)	(7,611)	(2,183)	(5,523)
GROSS PROFIT (LOSS)	1,452	1,636	(177)	835
RESEARCH AND DEVELOPMENT EXPENSES (1)	(14,762)	(15,271)	(7,476)	(9,304)
Less – grants	1,078	1,816	235	478
RESEARCH AND DEVELOPMENT EXPENSES, NET	(13,684)	(13,455)	(7,241)	(8,826)
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (2)	(4,656)	(5,351)	(2,158)	(2,814)
OPERATING LOSS	(16,888)	(17,170)	(9,576)	(10,805)
FINANCIAL EXPENSES	(4,013)	(5,132)	(1,793)	(3,045)
FINANCIAL INCOME	207	1,665	75	40
(LOSS) INCOME FROM CHANGE IN FAIR VALUE OF CONVERTIBLE NOTES EMBEDDED DERIVATIVE		(38,061)		14,260
FINANCIAL (EXPENSES) INCOME, NET	(3,806)	(41,528)	(1,718)	11,255
NET (LOSS) INCOME FOR THE PERIOD	$ (20,694)	$ (58,698)	$ (11,294)	$ 450
NET (LOSS) EARNINGS PER SHARE OF COMMON STOCK :				
BASIC				
Net (loss) earnings per share of common stock	$ (0.14)	$ (0.47)	$ (0.08)	$ 0.00
DILUTED				
Net loss per share of common stock	$ (0.14)	$ (0.47)	$ (0.08)	$ (0.06)
WEIGHTED AVERAGE NUMBER OF SHARES OF COMMON STOCK USED IN COMPUTING (LOSS) EARNINGS PER SHARE				
BASIC	145,985,445	126,000,782	146,644,450	127,523,706
DILUTED	145,985,445	126,000,782	146,644,450	192,598,389
(1) Includes share-based compensation	$ 40	$ 120	$ (2)	$ 55
(2) Includes share-based compensation	$ 34	$ 96	$ 14	$ 43