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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 8-K

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CURRENT REPORT  
Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934

Date of Report (Date of Earliest Event Reported): September 21, 2018

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**Protalix BioTherapeutics, Inc.**  
(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction  
of incorporation)

001-33357  
(Commission File Number)

65-0643773  
(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.)

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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. ☐

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**Item 7.01. Regulation FD Disclosure.**

On September 21, 2018, Protalix BioTherapeutics, Inc. (the “Company”) issued a press release announcing positive preliminary data from the BRIDGE study of pegunigalsidase alfa (PRX-102) for the treatment of Fabry disease. Additional data will be released at the 1st Canadian Symposium on Lysosomal Diseases 2018 which is will take place October 5-6, 2018 at the OLT Gouverneur Hotel in Sherbrooke, Quebec. 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 September 21, 2018.](#)

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## 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: September 21, 2018

By: /s/ Yossi Maimon  
Name: Yossi Maimon  
Title: Vice President and  
Chief Financial Officer

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**Protalix BioTherapeutics Reports Positive Preliminary Data from the BRIDGE Study of pegunigalsidase alfa for the Treatment of Fabry Disease**

*~Preliminary Results Indicate Improvement in Kidney Function in Patients Switched from agalsidase alfa (Replagal®) to pegunigalsidase alfa (PRX-102)~*

*A deterioration trend in patients' kidney function on agalsidase alfa (Replagal®) was reversed to an improvement trend when switched to pegunigalsidase alfa (PRX-102)*

*Presentation with full Data to be held at the 1st Canadian Symposium on Lysosomal Diseases 2018*

CARMIEL, Israel, September 21, 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 positive preliminary data from the BRIDGE study of pegunigalsidase alfa (PRX-102) for the treatment of Fabry disease. Additional data will be released at the 1st Canadian Symposium on Lysosomal Diseases 2018.

The BRIDGE study is an open label switch over study evaluating the safety and efficacy of PRX-102 in patients with Fabry disease currently treated with agalsidase alfa for at least 2 years and on a stable dose for at least 6 months. Patients are screened and evaluated over 3 months while continuing on agalsidase alfa. Following the screening period, each patient was enrolled and switched from agalsidase alfa treatment to receive intravenous (IV) infusions of PRX-102 1 mg/kg every two weeks for 12 months. Patients can receive PRX-102 infusions at a home care setup based on the infusion tolerability.

Preliminary data from the first sixteen patients enrolled in the trial demonstrated an improvement in kidney function when switched from agalsidase alfa (Replagal®) to pegunigalsidase alfa (PRX-102). Based on available historical serum creatinine and study 3 month screening period values for approximately 2 years while treated with agalsidase alfa before switching to pegunigalsidase alfa treatment, the annualized estimated glomerular filtration rate (eGFR) slope for patients on Replagal was (negative)  $-6.8\text{ml/min/1.73m}^2$ . The mean eGFR slope for the same patients following six months of treatment with pegunigalsidase alfa (PRX-102) was changed to be (positive) of  $+3.7\text{ml/min/1.73m}^2$ , these results were statistically significant. Baseline characteristic of these patients were: mean estimated glomerular filtration rate (eGFR) 75.40 and 86.03 mL/min/1.73m<sup>2</sup> for males and females, with annualized eGFR slope of -8.0 and -5.1 mL/min/1.73m<sup>2</sup>/year, respectively.

The BRIDGE study is an open-label, single arm switch-over study to assess the safety and efficacy of pegunigalsidase alfa, 1 mg/kg infused every two weeks, in 22 Fabry patients currently treated with Replagal. Protalix anticipates completing patient enrollment in the BRIDGE trial in the fourth quarter of 2018.

PRX-102 is the Company's plant cell-expressed recombinant, PEGylated, cross-linked  $\alpha$ -galactosidase-A for Fabry disease. In pre-clinical and clinical studies, PRX-102 demonstrated higher stability in plasma, a longer half-life and higher exposure in Fabry disease patients, and a reduction in Gb3 in kidney biopsies in treatment naïve Fabry patients.

**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 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 and the final results of a clinical trial may be different than the preliminary findings for the clinical trial. 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

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**Source: Protalix BioTherapeutics, Inc.**

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