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): February 10, 2020

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 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.001 par value	PLX	NYSE American

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 7.01 Regulation FD Disclosure

On February 10, 2020, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that one-year interim data from the ongoing Phase III BRIDGE clinical trial of the Company's pegunigalsidase alfa candidate (PRX-102) for the treatment of Fabry disease will be presented via a poster presentation at the 16th Annual WORLD*Symposium*™ 2020 in Florida, as well as other data.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Copies of the oral presentation and the posters will be made available on the Company's website under the Presentations tab in the Investors section.

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 February 10, 2020.

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: February 10, 2020

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan
Name: Dror Bashan
Title: President and
Chief Executive Officer

Exhibit 99.1

Protalix BioTherapeutics Presents Key Clinical Data of Pegunigalsidase Alfa for the Treatment of Fabry Disease at the 16th Annual WORLD*Symposium*™ 2020

- *Phase I/II dose-ranging studies show high correlation between two Fabry disease biomarkers, supporting potential effectiveness of pegunigalsidase alfa in treating Fabry disease*
- *12-Months on-treatment Phase III BRIDGE study interim data analysis indicates significant improvement in kidney function in patients switched from agalsidase alfa (Replagal®) to pegunigalsidase alfa (PRX-102)*
- *Oral presentation given by Dr. David Warnock on design and methods of pivotal Phase III BALANCE study testing PRX-102 versus the currently used enzyme replacement therapy, Fabrazyme® for Fabry patients with declining renal function*

CARMIEL, Israel, February 10, 2020 /PRNewswire/ -- Protalix BioTherapeutics, Inc. (NYSE American: PLX) (TASE: PLX), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx® plant cell-based protein expression system, announced today that one-year interim data from the ongoing Phase III BRIDGE clinical trial of the Company's pegunigalsidase alfa (PRX-102) candidate for the treatment of Fabry disease will be presented via a poster presentation at the 16th Annual WORLD*Symposium*™ 2020 in Florida.

The Company will also deliver additional data via a poster presentation on the Phase I/II dose-ranging studies of pegunigalsidase alfa for the treatment of Fabry disease, and both a poster and oral presentation on the design of the pivotal Phase III BALANCE clinical trial of pegunigalsidase alfa for the treatment of Fabry disease by David Warnock, M.D., University of Alabama at Birmingham, a principal investigator in the Company's BALANCE trial. The Company has already announced the schedule of the presentations.

The Company's BRIDGE clinical trial is a Phase III open-label single arm switch-over study evaluating the safety and efficacy of pegunigalsidase alfa, 1 mg/kg infused every two weeks, in up to 22 Fabry patients currently treated with agalsidase alfa (Replagal®) for at least two years and on a stable dose for at least six months.

The data to be presented via a poster by Dr. Ales Linhart of Charles University in Prague, Czech Republic, a principal investigator in the BRIDGE study, suggest that there exists a potential benefit of pegunigalsidase alfa on renal function for Fabry patients previously treated with agalsidase alfa.

"In addition to suggesting a positive safety and tolerability profile of pegunigalsidase alfa, these interim data indicate amelioration of the course of the disease," said Dr. Linhart. "While these results must be confirmed by the long-term data, all of the progressing patients and two-thirds of those in the 'fast progressing' group, to date, achieved the proposed therapeutic goals after switching to pegunigalsidase alfa, demonstrating substantial improvement in disease progression rate"

In previously announced interim data, pegunigalsidase alfa was found to be well tolerated in the study, with all adverse events being transient in nature without sequelae. As of today, the majority of patients who completed the study rolled over to a long-term extension study and continues to receive treatment. The BRIDGE study final results are expected by mid-2020.

Data on the Phase I/II dose ranging studies designed to evaluate the safety, efficacy and pharmacokinetics of pegunigalsidase alfa administered intravenously every other week in adult symptomatic, treatment-naïve male and female Fabry patients will be presented in a poster presentation by Prof. Derralynn Hughes of University College London (UK), a principal investigator in the Company's Phase III clinical trial of PRX-102.

"The results of this study demonstrate that pegunigalsidase alfa reaches the affected tissue and reduces the kidney Gb_3 inclusions burden and the Lyso-Gb_3 levels in circulation," said Prof. Hughes. "Further, the high correlation found between the two Fabry disease biomarkers, reduction of kidney Gb_3 inclusions and reduction of plasma Lyso-Gb_3 over six months of treatment, gives additional support to the potential effectiveness of pegunigalsidase alfa in treating Fabry disease."

An oral presentation, to be given by Dr. Warnock, describes the design and methods of the study protocol and the baseline characteristics for approximately 75 patients enrolled at 29 U.S. and European study sites.

The Company's Phase III BALANCE clinical trial is a fully enrolled, randomized, double blind, head-to-head active control study which aims to demonstrate pegunigalsidase alfa's superiority in kidney function over 24 months of treatment as compared to agalsidase beta (Fabrazyme®). The study enrolled adult Fabry patients that were previously treated with agalsidase beta with deteriorating renal function, where it is aimed to demonstrate clinical benefit on renal function post-switch to pegunigalsidase alfa versus patients remaining under agalsidase beta.

"The BALANCE study is designed to show pegunigalsidase alfa's solid potential to demonstrate clinical benefit in Fabry patients," said Dr. Warnock. "An improved Fabry treatment remains a significant unmet need for this underserved population, and we look forward to the completion of our study to help address this situation."

Copies of the oral presentation and the posters will be made available on the Company's website under the Presentations tab in the Investors section.

About Fabry Disease

Fabry disease is an X-linked inherited disease that results from deficient activity of the lysosomal α-Galactosidase-A enzyme resulting in progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide (Gb_3) in blood vessel walls throughout a person's body. Fabry disease occurs in one person per 40,000. Fabry patients inherit a deficiency of the α-Galactosidase-A enzyme, which is normally responsible for the breakdown of Gb_3. The abnormal storage of Gb_3 increases with time and, accordingly, Gb_3 accumulates, primarily in the blood and in the blood vessel walls. The ultimate consequences of Gb_3 deposition range from episodes of pain and impaired peripheral sensation to end-organ failure – particularly of the kidneys, but also of the heart and the cerebrovascular system.

About Pegunigalsidase Alfa

Pegunigalsidase alfa (PRX-102) is an investigational, plant cell culture-expressed, and chemically modified stabilized version of the recombinant α-Galactosidase-A enzyme. Protein sub-units are covalently bound via chemical cross-linking using short PEG moieties, resulting in a molecule with unique pharmacokinetic parameters. In clinical studies, PRX-102 has been observed to have a circulatory half-life of approximately 80 hours. The Company designed pegunigalsidase alfa to potentially address the continued unmet clinical need in Fabry patients of continuous disease progression, infusion reactions and immunogenicity.

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 was the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the 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 consists of proprietary, potentially clinically superior versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human α-Galactosidase-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 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: 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; and inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; the risk that the results of the clinical trials of our product candidates will not support our claims of 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 of our future revenues and expenditures; the risk that despite the FDA’s grant of fast track designation for PRX-102, 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; 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; 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.

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