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): May 11, 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**	**2161401**
(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 8.01 Other Events

On May 11, 2020, Protalix BioTherapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing positive topline results from its Phase III BRIDGE clinical trial of pegunigalsidase alfa, or PRX-102. Pegunigalsidase alfa is the Company's plant cell-expressed recombinant, PEGylated, cross-linked α-galactosidase-A product candidate under development for the treatment of Fabry disease. 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.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1	Press release dated May 11, 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: May 11, 2020

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Announces Positive Topline Results from the BRIDGE Phase III Open-Label, Switch-Over Clinical Trial Evaluating Pegunigalsidase Alfa for the Treatment of Fabry Disease

Phase III BRIDGE open-label, switch-over clinical trial met main objectives for safety and efficacy

Topline analysis indicates substantial improvement in renal function as measured by mean annualized estimated Glomerular Filtration Rate (eGFR slope) in patients switched from agalsidase alfa to pegunigalsidase alfa (PRX-102)

A decline trend in patients' renal function on agalsidase alfa was attenuated and improved to be similar to normal renal function decline when switched to PRX-102

CARMIEL, Israel, May 11, 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, today announced positive topline results from its Phase III BRIDGE clinical trial of pegunigalsidase alfa, or PRX-102. Pegunigalsidase alfa is the Company's plant cell-expressed recombinant, PEGylated, cross-linked α-galactosidase-A product candidate under development for the treatment of Fabry disease.

The BRIDGE study was a Phase III 12 month 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 previously treated with agalsidase alfa, marketed by Takeda Pharmaceutical Company Limited (Shire Plc) as Replagal®, for at least two years and on a stable dose for at least six months.

Topline results of the data generated in the study showed substantial improvement in renal function as measured by mean annualized estimated Glomerular Filtration Rate (eGFR slope) in both male and female patients who were switched from agalsidase alfa to PRX-102. Consistent with previously announced interim data, PRX-102 was found to be well tolerated, with all adverse events being transient in nature without sequelae. Twenty-two patients were enrolled in the study; two of those patients withdrew early from the study due to hypersensitivity reaction, and 20 of the patients successfully completed the 12-month treatment duration. Eighteen of the patients who completed the study opted to roll over to a long-term extension study and continue to be treated with PRX-102.

In the study, the mean annualized eGFR slope of the study participants improved from -5.90 mL/min/1.73m^2/year while on agalsidase alfa to -1.19 mL/min/1.73m^2/year on PRX-102 in all patients. Male patients improved from -6.36 mL/min/1.73m^2/year to -1.73 mL/min/1.73m^2/year and female patients improved from -5.03 mL/min/1.73m^2/year to -0.21 mL/min/1.73m^2/year.

Baseline characteristics of the patients, ranging from ages 24 to 60 years, were as follows: mean eGFR 75.87 mL/min/1.73m^2 in males and 86.14 mL/min/1.73m^2 in females and plasma lyso-Gb3 mean levels were 51.81 nM and 13.81 nM in males and females, respectively. While lyso-Gb3 levels remain slightly high, particularly within the male cohort, continuous reduction in lyso-Gb3 levels was observed of 19.55nM (32.35%) in males and 4.57nM (29.81%) in females.

“The final analysis of the BRIDGE Study in Fabry patients previously treated with agalsidase alfa demonstrate a positive potential benefit of pegunigalsidase alfa on renal function,” said Dr. Ales Linhart of Charles University in Prague, Czech Republic, a principal investigator in the BRIDGE study.

“The completion of our Phase III BRIDGE study and its subsequent analysis mark a significant milestone towards our goal to establish PRX-102 as a new treatment option for Fabry disease,” said Dror Bashan, Protalix’s President and Chief Executive Officer. “We are encouraged that the BRIDGE study successfully met its main objectives for safety and efficacy, and we are further motivated to continue our work in progressing pegunigalsidase alfa.”

“Our BRIDGE study, together with our other two ongoing fully enrolled Phase III clinical trials, the BALANCE study and the BRIGHT study, represents what we believe to be the most comprehensive and robust Phase III clinical program for Fabry disease currently in progress,” continued Mr. Bashan. “As the first of our three studies to complete Phase III, we believe the BRIDGE study findings support that PRX-102 has the potential to be an important enzyme replacement therapy for the treatment of Fabry disease.”

The ongoing BALANCE study is a fully enrolled, randomized, double blind, head-to-head, active control study which aims to demonstrate PRX-102’s superiority in renal function as measured by the comparison of the mean annualized change (slope) in estimated glomerular filtration rate ($eGFR_{CKD\text{-}EPI}$) between treatment groups over 24 months of treatment as compared to agalsidase beta, marketed by Sanofi Genzyme as Fabrazyme®. The BRIGHT study is a fully enrolled open-label, switch-over study designed to evaluate the safety, efficacy and pharmacokinetics of PRX-102, 2 mg/kg dosed once every 4 weeks, and to assess whether patients maintain clinical stability as measured by certain Fabry disease parameters after being switched to this regimen from an enzyme replacement therapy (ERT), agalsidase alfa or agalsidase beta, dosed every two weeks.

“We previously announced positive interim results from 16 Fabry patients after six and twelve months in the BRIDGE study. These final results not only indicate that our findings are durable and consistent with previous analyses, but also demonstrate the important potential benefit of pegunigalsidase alfa on renal function for Fabry patients,” said Einat Brill Almon, Ph.D., Protalix’s Senior Vice President, Product Development. “We look forward to the continued findings from our other ongoing Phase III studies of PRX-102, with the final results from the BRIGHT study expected in the fourth quarter of 2020, and interim results from the BALANCE study expected in the first half of 2021.”

As previously announced, the Company and its collaboration partner for PRX-102, Chiesi Farmaceutici S.p.A., or Chiesi, plan the submission of a BLA for PRX-102 via the FDA’s Accelerated Approval pathway in the second quarter of 2020. The Company and Chiesi have experienced minor delays in completing the submission due to the novel coronavirus disease (COVID-19) outbreak and other reasons, and the Company anticipates providing further updates regarding the planned submission by the end of the current month.

Additional Details about the BRIDGE Study

Patients in the BRIDGE study were screened and evaluated over three months while continuing agalsidase alfa treatment. Following the screening period, each patient was enrolled and switched from agalsidase alfa treatment to receive intravenous infusions of PRX-102, 1 mg/kg every two weeks, for 12 months. Patients had the option to receive PRX-102 infusions in a home care setting based on infusion tolerability and country regulation.

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 to 60,000. 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 PRX-102 to potentially address the continued unmet clinical need in 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 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 proposed 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; risks associated with the novel coronavirus disease (COVID-19) outbreak, which may adversely impact our business, preclinical studies and clinical trials; 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.

Investor Contact
Chuck Padala, Managing Director
LifeSci Advisors
646-627-8390
chuck@lifesciadvisors.com

Media Contact
Brian Pinkston
LaVoieHealthScience
857-588-3347
bpinkston@lavoiehealthscience.com

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