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 6, 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** **(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))

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 February 6, 2020, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing, together with its development and commercialization partner, Chiesi Farmaceutici S.p.A., an agreement with the U.S. Food and Drug Administration ("FDA") for the Initial Pediatric Study Plan ("iPSP") for pegunigalsidase alpha (PRX-102). The companies reported the news after completing discussions with the FDA and receiving confirmation in an official "Agreement Letter" which outlines an agreed approach to address the needs of pediatric patients with 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 February 6, 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 6, 2020

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics and Chiesi Farmaceutici Announce Receipt of "Agreement Letter" for Initial Pediatric Study Plan for PRX-102 for the Treatment of Fabry Disease

CARMIEL, Israel, February 6, 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, and its development and commercialization partner, Chiesi Farmaceutici S.p.A. (Chiesi), an international research-focused healthcare group, today announced an agreement with the U.S. Food and Drug Administration (FDA) for the Initial Pediatric Study Plan (iPSP) for pegunigalsidase alpha, or PRX-102. The companies reported the news after completing discussions with the FDA and receiving confirmation in an official "Agreement Letter" which outlines an agreed approach to address the needs of pediatric patients with Fabry disease.

PRX-102 is the Company's plant cell-expressed recombinant, PEGylated, cross-linked α-galactosidase-A candidate for the treatment of Fabry disease. PRX-102 has the potential to be approved for adult patients with Fabry disease under the FDA's Accelerated Approval pathway.

"Proceeding with the pediatric study plan for PRX-102 marks an important milestone in our goal of bringing an alternative to the Fabry patient community which is in need of better treatment options other than those currently available," said Dror Bashan, Protalix BioTherapeutics' President and Chief Executive Officer.

Together with our partner Chiesi, we value this pediatric study as a new opportunity to potentially bring a new treatment option to the entire Fabry community." said Dr. Raul Chertkoff, Protalix BioTherapeutics' Vice President, Medical Affairs.

The Company and Chiesi have previously reported that they expect to submit a Biologics License Application (BLA) to the FDA under an Accelerated Approval pathway. Based on prior discussions with the FDA, the companies believe that the nonclinical data, the clinical data, the safety database and manufacturing data are sufficient to support the BLA submission.

About Fabry Disease

Fabry disease is an X-linked inherited disease that results from deficient activity of the lysosomal enzyme α-galactosidase-A resulting in progressive accumulation of abnormal deposits of a fatty substance called globotriaosylceramide (Gb3) 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 enzyme alpha-galactosidase-A, which is normally responsible for the breakdown of Gb3. The abnormal storage of Gb3 increases with time and, accordingly, Gb3 accumulates, primarily in the blood and in the blood vessel walls. The ultimate consequences of Gb3 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 of continuous disease progression, infusion reactions and immunogenicity.

About the Chiesi Group

Based in Parma, Italy, Chiesi Farmaceutici is an international research-oriented group with over 80 years' experience in the pharmaceutical sector and is present in 28 countries. The Group researches, develops and commercializes innovative medicines in respiratory disease, special care and rare disease therapeutic areas. The Group's Research & Development center is integrated with six other important research and development groups in France, the USA, the UK and Sweden, to promote its pre-clinical, clinical and registration programs. The Group employs around 5,700 people. Chiesi Group is a certified B Corp. For more information, please visit www.chiesi.com.

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; 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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