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): July 24, 2018 (July 23, 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**	**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 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. ☐

Item 1.01. Entry into a Material Definitive Agreement

On July 24, 2018, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that the Company's wholly-owned subsidiary, Protalix Ltd. ("Protalix"), entered into an Exclusive License and Supply Agreement, dated July 23, 2018 (the "U.S. License Agreement"), with Chiesi Farmaceutici S.p.A. ("Chiesi"), to develop and commercialize in the United States pegunigalsidase alfa, or PRX-102, the Company's chemically modified version of the recombinant protein alpha-Galactosidase-A protein that is currently being evaluated in phase III clinical trials for the treatment of Fabry disease. As announced in October 2017, Protalix and Chiesi are parties to a separate exclusive license and supply agreement, pursuant to which Protalix granted to Chiesi exclusive licensing rights for the commercialization of PRX-102 for all markets outside of the United States.

Under the terms of the U.S. License Agreement, Protalix is entitled to an upfront, non-refundable, non-creditable payment of $25 million from Chiesi, and additional payments of up to a maximum of $20 million to cover Protalix's development costs for PRX-102, subject to a maximum of $7.5 million per year. Protalix is also eligible to receive an additional up to a maximum of $760 million, in the aggregate, in regulatory and commercial milestone payments.

Protalix and Chiesi have agreed to a specific allocation of the responsibilities for the continued development efforts for PRX-102. Protalix will manufacture all of the PRX-102 needed for clinical development and commercial purposes, subject to certain exceptions, and Chiesi will purchase PRX-102 from Protalix, subject to certain terms and conditions. Chiesi will make tiered royalty payments of 15% to 40% on net sales, depending on the amount of annual sales subject to certain terms and conditions, as consideration for product supply. The U.S. License Agreement also provides for reimbursement by Chiesi of certain costs to be incurred by Protalix.

The U.S. License Agreement includes customary termination, confidentiality, indemnification and other provisions. The foregoing description of the U.S. License Agreement does not purport to be complete and is qualified in its entirety by the U.S. License Agreement, a copy of which the Company intends to file as an exhibit to the Company's periodic reports.

Item 8.01. Other Events

On July 24, 2018, the Company issued a press release announcing the entry into the U.S. License Agreement. 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 July 24, 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.

PROTALIX BIOTHERAPEUTICS, INC.

Date: July 24, 2018

By: /s/ Moshe Manor
Name: Moshe Manor
Title: President and
Chief Executive Officer

Exhibit 99.1

Protalix BioTherapeutics Expands Partnership with Chiesi Farmaceutici to Include Exclusive U.S. Rights for the Development and Commercialization of PRX-102 (pegunigalsidase alfa) for the Treatment of Fabry Disease

Protalix to receive $25 million upfront, an additional up to $20 million in development costs and an additional up to $760 million in potential regulatory and commercial milestone payments for the U.S. rights

U.S. partnership includes tiered royalties ranging from 15% to 40% on net sales

CARMIEL, Israel, July 24, 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 the expansion of its partnership with Chiesi Farmaceutici S.p.A., or Chiesi. Protalix and Chiesi entered into an exclusive U.S. license and supply agreement which grants to Chiesi the United States rights for the development and commercialization of PRX-102 (pegunigalsidase alfa), the Company's chemically modified version of the recombinant protein alpha-Galactosidase-A protein, for the treatment of Fabry disease. In October 2017, Protalix announced an exclusive partnership with Chiesi for the development and commercialization of PRX-102 for the treatment of Fabry disease outside the United States.

Under the terms of the U.S. license and supply agreement, Protalix is entitled to an upfront payment of $25 million from Chiesi and additional payments of up to a maximum of $20 million in development costs, capped at $7.5 million per year. Protalix is also eligible to receive an additional up to a maximum of $760 million, in the aggregate, in regulatory and commercial milestone payments, and tiered royalties ranging from 15% to 40% on net sales as consideration for product supply. Protalix will continue to be the manufacturer of PRX-102 for clinical development and commercial purposes.

"We are very pleased to expand our collaboration with Chiesi, a growing global company with well-established global commercial infrastructure with a fast growing commercial presence in the U.S. Chiesi's global investment of $95 million in upfront payments and development costs reimbursement, and additional up to a maximum of $1 billion in potential milestone payments, combined in the two agreements reflects Chiesi's true commitment to the Fabry space," commented Moshe Manor, Protalix's President and Chief Executive Officer. "Taking into consideration a $25 million upfront payment and shared development expenses, we expect our cash runaway to take us through the read outs of all of the Fabry clinical trials."

In pre-clinical trials, PRX-102 demonstrated a significantly enhanced circulatory half-life and higher enzyme activity in the target organs affected by Fabry disease when compared to currently available versions of the molecule. In clinical development, PRX-102 demonstrated strong positive safety and efficacy data in a phase I/II clinical trial. Fabry patients are currently being enrolled in a global, pivotal phase III clinical trial, and Protalix anticipates starting to report data from these studies in the first half of 2019.

"We believe PRX-102 has the potential to transform the treatment of Fabry disease and are excited to now have exclusive commercial rights to PRX-102 worldwide," said Ugo Di Francesco, Chiesi's Chief Executive Officer. "The more we work with Protalix and see the progress made in the development and the product's characteristics, it becomes abundantly clear the significant role PRX 102 could have in the underserved Fabry market and to potentially change the treatment paradigm to the benefit of all stake holders. We believe this U.S. license agreement will bring many synergies in our fast growing U.S. presence in rare diseases."

Additional details regarding the collaboration can be found in Protalix's Form 8-K to be filed with the Securities and Exchange Commission.

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.

About Chiesi Farmaceutici S.p.A.

Based in Parma, Italy, Chiesi Farmaceutici is an international research-focused Healthcare Group, with over 80 years of experience in the pharmaceutical industry. Chiesi researches, develops and markets innovative drugs in the respiratory therapeutics, specialist medicine and rare disease areas. Its R&D organization is headquartered in Parma (Italy), and integrated with 6 other key R&D groups in France, the USA, the UK, Sweden and Denmark to advance Chiesi's pre-clinical, clinical and registration programmes. Chiesi employs nearly 5,300 people. For more information, visit www.chiesi.com.

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 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; risks related to the amount and sufficiency of our cash and cash equivalents; 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.

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Source: Protalix BioTherapeutics, Inc.