Protalix BioTherapeutics, Inc.
Form 8-K
July 24, 2018

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** **(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 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