

Protalix BioTherapeutics, Inc.
Form 8-K
October 13, 2015

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): October 13, 2015 (October 12, 2015)

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Florida **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) (Zip Code)

20100

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 communications 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))

Item 1.01. Entry into a Material Definitive Agreement

On October 13, 2015, Protalix BioTherapeutics, Inc. (the “Company”) announced that its wholly-owned subsidiary, Protalix Ltd. (“Protalix”), had entered into an Amended and Restated Exclusive License and Supply Agreement, dated October 12, 2015 (the “Amended Agreement”), with Pfizer Inc. (“Pfizer”). The Amended Agreement amends and restates, in its entirety, that certain Exclusive License and Supply Agreement dated November 30, 2009 by and between Protalix and Pfizer, as amended on June 18, 2013 (the “Original Agreement”). Pursuant to the Amended Agreement, Protalix has sold its share in the collaboration with Pfizer on the commercialization of Elelyso™ to Pfizer in exchange for a cash payment equal to \$36 million. As part of the sale, Protalix agreed to transfer its rights to Elelyso in Israel to Pfizer, and has retained rights to Elelyso in Brazil. Under the Original Agreement, Pfizer and Protalix shared in revenues and expenses for the development and commercialization of Elelyso on a 60%/40% basis globally, excluding Israel and Brazil. Under the Amended Agreement, Pfizer is responsible for 100% of expenses, and entitled to all of the revenues, globally for Elelyso, excluding Brazil, where Protalix is responsible for all expenses and retains all revenues. The Amended Agreement eliminates Pfizer’s entitlement to annual payments of up to \$12.5 million in relation to commercialization of Elelyso in Brazil.

For the first ten year period after the execution of the Amended Agreement, Protalix shall continue to sell drug substance to Pfizer for the production of Elelyso, and Pfizer maintains the right to extend the supply period for up to two additional 30-month periods. The Amended Agreement also includes provisions regarding cooperation for regulatory matters, supply of the drug substance to Pfizer, including provisions addressing failure to supply, and patent enforcement, and contains customary provisions regarding termination, indemnification and insurance requirements.

The Amended Agreement includes a non-competition covenant which limits Protalix’s right to commercialize any drug product or compound for the treatment of Gaucher disease, other than Protalix’s oral formulation, for a specified period and subject to specified exceptions.

In addition to the foregoing, the Amended Agreement provides that Protalix shall issue to Pfizer a five-year, non-interest bearing promissory note with a principal amount equal to approximately \$4.3 million for accumulated losses of the collaboration through September 30, 2015. The note includes standard events of default that result in the acceleration of the note’s maturity date. In addition, the note becomes immediately payable upon certain failures by Protalix to supply drug substance to Pfizer under the Amended Agreement.

Item 2.02. Results of Operations and Financial Condition

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On October 13, 2015, the Company issued a press release announcing the entry into the Amended Agreement described in Item 1.01. The press release includes certain information regarding the Company's financial condition as of September 30, 2015. See Item 8.01.

In accordance with General Instruction B.2 of Form 8-K, the information regarding the Company's financial condition as of September 30, 2015 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 (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 3.02. Unregistered Sales of Equity Securities

On October 12, 2015, the Company entered into a Stock Purchase Agreement with C.P. Pharmaceuticals International C.V. (the “Purchaser”), an affiliate of Pfizer, pursuant to which the Company agreed to sell, and the Purchaser agreed to buy, 5,649,079 shares of the Company’s common stock for an aggregate purchase price equal to \$10,000,000 subject to certain other terms set forth in the Stock Purchase Agreement. The issuance is exempt from registration pursuant to Section 4(a)(2) of the Securities Act. As part of the Stock Purchase Agreement, Pfizer has agreed to a 180-day lock-up with respect to the purchased shares of common stock and the Company’s directors and executive officers have entered into 90-day lock up agreements.

Item 8.01. Other Events

On October 13, 2015, the Company issued a press release announcing the entry into the Amended 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, except to the extent set forth in Item 2.02.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated October 13, 2015.

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: October 13, 2015 By: /s/ Moshe Manor
Name: Moshe Manor
Title: President and Chief Executive Officer