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**	**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 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

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

Protalix BioTherapeutics Sells its Share in Collaboration Agreement for ELELYSO and a 6% Equity Stake in Protalix to Pfizer for a total of $46 Million

Protalix to use funds to aggressively push its clinical pipeline forward and execute its new strategy of developing clinically superior biologics

Protalix receives all rights to ELELYSO in Brazil in exchange for all rights to ELELYSO in Israel

CARMIEL, Israel, October 13, 2015 -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that the Company sold its share in the collaboration agreement for ELELYSO™ to its commercialization partner, Pfizer Inc. Under the initial collaboration agreement, Pfizer and the Company shared revenues and expenses for the development and commercialization of ELELYSO on a 60%/40% basis globally, excluding Israel and Brazil. As amended, Pfizer is responsible for 100% of expenses, and entitled to all of the revenues, globally for ELELYSO, excluding Brazil, where the Company will be responsible for all expenses and retain all revenues.

“We are very pleased to have the support of Pfizer as a shareholder of the Company. The funds we are receiving from the overall transaction, totaling $46 Million, will yield a strong pro forma cash balance for the Company of approximately $80 Million as of September 30, 2015 enabling us to aggressively push our clinical pipeline forward and concentrate on our new strategy of developing clinically superior biologics” said Moshe Manor, Protalix’s President and Chief Executive Officer. “Additionally, we are very happy to restructure and extend our existing relationship with Pfizer as they have shown their commitment to Gaucher patients and treating physicians.”

Pursuant to the amended collaboration agreement, the Company will receive $36 Million in cash from Pfizer for the Company’s share in the collaboration agreement and the Israeli territory, while Pfizer will transfer to the Company full commercialization rights in Brazil thereby eliminating annual payments of up to $12.5 Million to which Pfizer was entitled.

In addition to the $36 Million cash payment, pursuant to a stock purchase agreement, Pfizer agreed to make a $10 Million investment in exchange for 5,649,079 shares of the Company’s common stock subject to certain other terms referenced under the stock purchase agreement.

“We look forward to expanding the availability of ELELYSO and our successful patient support programs to the Gaucher patient community globally,” said Michael Goettler, Global Commercial Officer, Global Innovative Pharma Business, Pfizer Inc. “This amended agreement underscores Pfizer’s long-standing commitment to serving the needs of patients living with rare diseases.”

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, by Israel's Ministry of Health in September 2012, by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013, and by the regulatory authorities of other countries. Protalix's development pipeline includes the following product candidates: PRX-102, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; PRX-112, an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, for the treatment of Gaucher disease; PRX-106, an orally-delivered anti-inflammatory treatment; PRX-110 for the treatment of Cystic Fibrosis; and others.

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 "anticipate," "believe," "estimate," "expect," "plan" 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: risks relating to the non-compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement for Brazil; risks related to the commercialization efforts for taliglucerase alfa in Brazil; failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: lack of sufficient funding to finance clinical trials; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; inability to monitor patients adequately during or after treatment; and the 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; 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 release are valid only as of the date hereof and we disclaim any obligation to update this information.

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Source: Protalix BioTherapeutics, Inc.