Protalix BioTherapeutics, Inc.
Form 8-K
June 19, 2013

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): June 18, 2013

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)**	**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 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 June 18, 2013, Protalix Ltd. (“Protalix”), a wholly-owned subsidiary of Protalix BioTherapeutics, Inc. (the “Company”), entered into a Supply and Technology Transfer Agreement with Fundação Oswaldo Cruz, commonly referred to as Fiocruz, an arm of the Brazilian Ministry of Health for UPLYSO™ (alfa-taliglicerase), the Company’s proprietary enzyme replacement therapy for the treatment of Gaucher disease.

The technology transfer is expected to take place during a seven-year term in four stages and is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high quality, and cost effective supply of UPLYSO. Under the agreement, Fiocruz has committed to purchase at least approximately US$40 million worth of UPLYSO during the first two years of the agreement. In subsequent years, Fiocruz is required to purchase at least approximately US$40 million worth of UPLYSO per year. Additionally, the Company is not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately US$280 million worth of UPLYSO. The agreement may be extended for an additional five-year term, as needed, to complete the technology transfer. All of the terms of the arrangement, including the minimum annual purchases, will apply during the additional term.

Upon completion of the technology transfer, and subject to Fiocruz receiving approval from the Brazilian National Health Surveillance Agency (ANVISA) to manufacture UPLYSO in its facility in Brazil, the agreement will enter into the final term and will remain in effect until the Company’s last patent in Brazil expires. During such period, Fiocruz will be the sole provider of UPLYSO in Brazil and shall pay the Company a single-digit royalty on net sales.

The agreement will become effective after the parties receive approval of the agreement by the Brazilian National Institute of Industrial Property, which is expected to occur within approximately a month of the signature date of the agreement. The agreement may be terminated by the Company in the event of certain breaches of representations and warranties by Fiocruz; certain material defaults by Fiocruz in the performance of its obligations under the agreement; any privatization of Fiocruz or acquisition of Fiocruz by a competitor of the Company; any failure by Fiocruz to make payments under the agreement, subject to the right to cure; certain changes of control of Fiocruz; if Fiocruz fails to meet certain specified purchase requirements; in certain bankruptcy-related situations; and others. The agreement may be terminated by Fiocruz in the event of certain breaches of representations and warranties by the Company; certain material defaults by the Company in the performance of its obligations under the agreement; if, due to changes in Brazilian law, Fiocruz is unable to comply with the agreement; and if prGCD, in its finished dosage form, is recalled by ANVISA and the U.S. Food and Drug Administration. Upon any termination of the agreement, all licenses and rights granted to Fiocruz under the agreement shall terminate.

The Company and Fiocruz agreed to indemnify each other for certain losses under the agreement.

UPLYSO is marketed as ELELYSO™ in the United States and Israel.

To facilitate the arrangement with Fiocruz, the Company's commercialization partner for UPLYSO, Pfizer Inc., amended its exclusive license and supply agreement with the Company. The amendment provides for the transfer of the commercialization and other rights to UPLYSO in Brazil back to the Company.

As consideration for the transfer of the commercialization and supply agreements, the Company agreed to pay Pfizer a maximum amount of approximately $12.5 million from its net profits (as defined in the agreement) per year. Pfizer has also agreed to perform certain transitional services on the Company’s behalf in connection with the supply of UPLYSO to Fiocruz and the technology transfer.

The Company will pay a fee equal to 5% of the net proceeds generated in Brazil to its agent for services provided in assisting the Company complete the agreement pursuant to an agency agreement between the Company and the agent. The agency agreement will remain in effect with respect to the supply and technology transfer agreement or any other similar agreement until the termination of the applicable agreement.

Item 8.01. Other Events

On June 19, 2013, Protalix BioTherapeutics, Inc. issued a press release announcing that it has entered into the supply and technology transfer agreement with Fiocruz, as described in Item 1.01.

The Company’s management will discuss certain terms and conditions of the agreement during its previously scheduled analyst event on Thursday, June 20, 2013 at 8:00 AM EDT. The event audio and slide presentation will be webcast live and archived on the Company’s website for a 30-day period. The webcast will be available at www.protalix.com on the Events Calendar page. The slides will be available under the presentation tab on the Company’s website after the presentation.

A copy of the press release is filed as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated June 19, 2013.

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: June 19, 2013	By:	/s/ David Aviezer
	Name:	David Aviezer, Ph.D.
	Title:	President and Chief Executive Officer