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**	**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 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

Exhibit 99.1

Protalix BioTherapeutics and Brazil's Ministry of Health Enter into Supply and Technology Transfer Agreement for UPLYSO™ (alfataliglicerase) in Brazil

Exclusive License and Supply Agreement with Pfizer amended to facilitate the Technology Transfer

CARMIEL, Israel, June 19, 2013 /GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX, TASE:PLX), announced today that it has 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™ (alfataliglicerase), the Company's proprietary enzyme replacement therapy for the treatment of Gaucher disease. Gaucher disease is a rare lysosomal storage disorder that affects approximately 10,000 people worldwide.

The technology transfer is expected to take place during a seven-year term 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, Protalix 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.

"We are excited to be working with the Brazilian government in its efforts to provide UPLYSO to Gaucher patients in Brazil and to collaborate with Fiocruz regarding our plant cell technology," said Dr. David Aviezer, Protalix BioTherapeutics' President and Chief Executive Officer. "We are encouraged by the recognition of our drug and our technology by both Fiocruz and Brazil's Ministry of Health, and believe that this agreement will further establish a reliable supply of treatment for patients living with Gaucher disease."

The technology transfer agreement becomes effective after the parties receive approval of the agreement by the Brazilian National Institute of Industrial Property, which is expected to occur in approximately one month. During the technology transfer period, Fiocruz will apply for its own registration of UPLYSO with the Brazilian National Health Surveillance Agency (ANVISA, Agencia Nacional de Vigilancia Sanitaria) and continue to make the product available. Once the technology transfer is complete, the government will be the sole source of this important treatment option for Gaucher patients in Brazil.

"It is an honor to announce this agreement with Protalix for the supply and production of UPLYSO in Brazil," commented Dr. Alexandre Padilha, Brazil's Minister of Health."Through this collaboration, we are able to strengthen our technological and industrial capabilities in the area of biologics manufacturing and improve the health of Brazilian citizens who are impacted by this rare disorder."

In March 2013, the Brazilian National Health Surveillance Agency (ANVISA, Agencia Nacional de Vigilancia Sanitaria) granted regulatory approval to Pfizer for UPLYSO which is indicated for the long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type I Gaucher disease.

To facilitate the arrangement with Fiocruz, the Company's commercialization partner for UPLYSO, Pfizer Inc., amended its exclusive license and supply agreement and returned commercialization rights in Brazil to the Company. In consideration for the return of these rights, the Company will pay Pfizer a maximum amount of approximately US$12.5 million from the Company's net profits generated in Brazil per year of the agreement. During the transition of commercial rights back to the Company, Pfizer will continue to support Gaucher disease patients in Brazil who are being treated with UPLYSO.

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 to complete the agreement.

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

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.

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, by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in April 2013, and by the regulatory authorities of other countries. Marketing applications for taliglucerase alfa have been filed in additional territories as well. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of taliglucerase alfa, excluding Israel, where Protalix retains full rights. Protalix's development pipeline also 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-105, a pegylated recombinant human acetylcholinesterase in development for several therapeutic and prophylactic indications, a biodefense program and an organophosphate-based pesticide treatment program; an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, also for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel®) for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis; 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 related to the acceptance and use of UPLYSO by physicians, patients and the Brazilian Ministry of Health; risks related to our and Fiocruz's ability to market UPLYSO to the Brazilian Ministry of Health; our dependence on performance by third party providers of services and supplies relating to the commercialization of taliglucerase alfa in Brazil; 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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