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 7, 2016

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**	**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 8.01. Other Events

On July 7, 2016, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that the first patient has been dosed in the Company's phase II clinical trial of AIR DNase™ (PRX-110) for the treatment of Cystic Fibrosis (CF). AIR DNase is a plant cell derived recombinant form of human deoxyribonuclease I (DNase I) that is designed through chemical modification to be resistant to inhibition by actin. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1 Press release dated July 7, 2016.

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 7, 2016

By: /s/ Moshe Manor
Name: Moshe Manor
Title: President and
Chief Executive Officer

Exhibit 99.1

Protalix BioTherapeutics Announces First Patient Dosed in the AIR DNase™ Phase II Clinical Trial for Cystic Fibrosis

CARMIEL, Israel, July 7, 2016 -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today the first patient has been dosed in the Company's phase II clinical trial of AIR DNase™ (PRX-110) for the treatment of Cystic Fibrosis (CF). AIR DNase is a plant cell derived recombinant form of human deoxyribonuclease I (DNase I) that the Company has designed, through chemical modification, to be resistant to inhibition by actin. Given actin is a potent inhibitor of DNase I activity, the Company's AIR DNase has the potential to enhance the enzyme's efficacy significantly in CF patients when compared to the currently approved DNase treatment (Pulmozyme®).

The phase II trial is a 28-day switch-over study of 15 CF patients previously treated with Pulmozyme® to evaluate the efficacy and safety of AIR DNase in CF patients. The patients will undergo a two-week washout period, in which they will not be treated with Pulmozyme, before dosing with the Company's AIR DNase. The main efficacy endpoint is the change from baseline of forced expiratory volume (FEV1) and forced vital capacity (FVC). Additional endpoints include safety and tolerability, immunogenicity and pharmacokinetic data.

"We are very excited to begin treating CF patients with AIR DNase in the clinical trial setting," said Moshe Manor, Protalix's President and Chief Executive Officer. "We believe that our unique enzyme modification, which allows the enzyme to resist actin inhibition, has the potential to set our enzyme apart from the approved enzyme replacement therapy available today. This is the Company's second product currently in clinical trials in patients, following PRX-102 for the treatment of Fabry disease, that was specifically designed to be superior to existing products with the potential to garner significant market share in their respective categories."

The Company has signed a supply agreement with Philips Respironics for its I-neb AAD Inhaler System which gives the Company exclusive use of the device for the development of an inhaled product based on dornase alfa for the treatment of CF, and the Company is using the device to deliver AIR DNase in the clinical trial. The I-neb AAD is a small, lightweight, virtually silent device that is fully portable and has a unique vibrating mesh technology that allows for faster administration than conventional jet or ultrasonic nebulizers.

The phase II clinical trial is expected to complete enrollment in the second half of 2016. Top-line results are expected to be available around year-end.

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 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights. Protalix's development pipeline includes the following product candidates: PRX-102, a pegylated version of a recombinant human alpha-GAL-A protein for the treatment of Fabry disease; PRX-106, an orally-delivered anti-inflammatory treatment; PRX-110, a chemically modified DNase I 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: failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and lack of sufficient funding to finance clinical trials; 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.

Investor Contact

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Source: Protalix BioTherapeutics, Inc.