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): May 26, 2022

Protalix BioTherapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-33357 (Commission File Number)

65-0643773 (IRS Employer **Identification No.)**

2 University Plaza Suite 100 Hackensack, NJ (Address of principal executive offices)

07601 (Zip Code)

Registrant's telephone number, including area code 201-696-9345

(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 communication 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value	PLX	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company \Box

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 7.01 Regulation FD Disclosure

On May 26, 2022, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that five poster presentations are scheduled to be available at the 2022 Program: 7th Update on Fabry Disease: Biomarkers, Progression and Treatment Opportunities. A copy of the poster presentations from the program, as well as abstracts describing results from certain of the Company's clinical trials that are going to be distributed at the program, will be available on Protalix's website under the Presentation tab in the Investors section. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K ("Current Report").

In accordance with General Instruction B.2 of Form 8-K, the information 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

Exhibit No.

Description

99.1Press Release dated May 26, 2022104Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: May 26, 2022

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan

Name: Dror Bashan Title: President and Chief Executive Officer



Protalix BioTherapeutics Announces Poster Presentations at the 2022 Program: 7th Update on Fabry Disease

CARMIEL, Israel, May 26, 2022 -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development, production and commercialization of recombinant therapeutic proteins produced by its proprietary ProCellEx[®] plant cell-based protein expression system, today announced that five poster presentations are scheduled to be available at the 2022 Program: 7th Update on Fabry Disease: Biomarkers, Progression and Treatment Opportunities. The program is supported by Kidneys for Life, a Registered UK Charitable Organization (Manchester, UK), and is taking place May 29, 2022 through May 31, 2022 at the Maritim Hotel and Conference Center, Würzburg Germany.

The following poster presentations are planned to be available at the program:

"Safety and Efficacy of Pegunigalsidase Alfa vs Agalsidase Beta on Renal Function in Fabry Disease: 24-Month Results from the Phase III Randomized, Double-blind, BALANCE Study"

"Long-term Safety and Efficacy of Pegunigalsidase Alfa: A Multicenter Extension Study in Adult Patients with Fabry Disease"

"Tolerability and Infusion Duration of Pegunigalsidase Alfa in Patients with Fabry Disease: Data from 5 Completed Clinical Trials"

"Switching from Agalsidase Alfa to Pegunigalsidase Alfa to Treat Patients with Fabry Disease: 1 Year of Treatment Data from BRIDGE, a Phase 3 Open-label Study"

"Safety and Efficacy of Pegunigalsidase Alfa Administered Every 4 Weeks in Patients with Fabry Disease: Results from the Phase 3, Open-label, BRIGHT Study"

A copy of the poster presentations from the program, as well as abstracts describing results from certain of the Company's clinical trials that are going to be distributed at the program, will be available on Protalix's website under the Presentation tab in the Investors section.

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 was the first company to gain U.S. Food and Drug Administration (FDA) approval of a protein produced through plant cell-based in suspension expression system. Protalix's unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner.

Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved by the 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 consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: pegunigalsidase alfa, a modified stabilized version of the recombinant human α -Galactosidase-A protein for the treatment of Fabry disease; alidornase alfa or PRX-110, for the treatment of various human respiratory diseases or conditions; PRX-115, a plant cell-expressed recombinant PEGylated uricase for the treatment of NETs-related diseases; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

Investor Contact

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