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 25, 2024

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 University Plaza Suite 100 Hackensack, NJ		**07601**
(Address of principal executive offices)		**(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 ☐

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. ☐

Item 7.01 Regulation FD Disclosure

On October 25, 2024, Protalix BioTherapeutics, Inc. (the "Company") issued a press release announcing that data from the phase I clinical trial of PRX-115, the Company's recombinant PEGylated uricase product candidate in development for the treatment of uncontrolled gout, will be presented in a late-breaking poster at the American College of Rheumatology (ACR) Convergence 2024, being held November 14-19, 2024 at the Walter E. Washington Convention Center in Washington, D.C. The press release also disclosed that an abstract containing data generated in the trial may be accessed on the ACR Convergence 2024 website at https://acrabstracts.org/abstract/prolonged-plasma-urate-lowering-after-a-single-intravenous-administration-of-prx-115-a-novel-pegylated-uricase-in-participants-with-elevated-urate-levels/. 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, 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
99.1	Press Release dated October 25, 2024
104	Cover 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: October 25, 2024

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan
Name: Dror Bashan
Title: President and Chief Executive Officer

Exhibit 99.1

Protalix BioTherapeutics to Present Phase I PRX-115 Data in Late-Breaking Poster at ACR Convergence 2024

CARMIEL, Israel, October 25, 2024 -- Protalix BioTherapeutics, Inc. (NYSE American: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 data from the phase I clinical trial of PRX-115, the Company's recombinant PEGylated uricase product candidate in development for the treatment of uncontrolled gout, will be presented in a late-breaking poster at the American College of Rheumatology (ACR) Convergence 2024, being held November 14-19, 2024 at the Walter E. Washington Convention Center in Washington, D.C.

Details of the presentation are as follows:

ACR Convergence 2024

Title:	Prolonged Plasma Urate-Lowering After a Single Intravenous Administration of PRX-115, a Novel PEGylated Uricase, in Participants with Elevated Urate Levels
Session:	Late-Breaking Posters (L01-L14)
Session Date/Time:	Monday, November 18, 2024, 10:30 AM – 12:30 PM Eastern Standard Time
Presenting Author:	Orit Cohen Barak, Ph.D. (Protalix Ltd.)
Abstract Number:	L05

The accepted abstract can be accessed on the ACR Convergence 2024 website at https://acrabstracts.org/abstract/prolonged-plasma-urate-lowering-after-a-single-intravenous-administration-of-prx-115-a-novel-pegylated-uricase-in-participants-with-elevated-urate-levels/. A copy of the poster will be made available on the Protalix website.

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. It is 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. This unique expression system represents a new method for developing recombinant proteins in an industrial-scale manner. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights to taliglucerase alfa for the treatment of Gaucher disease, Protalix's first product manufactured through ProCellEx, excluding in Brazil, where Protalix retains full rights. Protalix's second product, Elfabrio®, was approved by both the FDA and the European Medicines Agency in May 2023.

Protalix has partnered with Chiesi Farmaceutici S.p.A. for the global development and commercialization of Elfabrio. Protalix's development pipeline consists of proprietary versions of recombinant therapeutic proteins that target established pharmaceutical markets, including the following product candidates: PRX–115, a plant cell-expressed recombinant PEGylated uricase for the treatment of uncontrolled gout; PRX–119, a plant cell-expressed long action DNase I for the treatment of NETs–related diseases; 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 “expect,” “anticipate,” “believe,” “estimate,” “project,” “may,” “plan,” “will,” “would,” “should” 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 and the final results of a clinical trial may be different than the preliminary findings for the clinical trial. Factors that might cause material differences include, among others: failure or delay in the commencement or completion of 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 satisfactorily demonstrate non-inferiority to approved therapies; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; inability to monitor patients adequately during or after treatment; and/or lack of sufficient funding to finance our clinical trials; the risk 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; 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; potential product liability risks, and risks of securing adequate levels of related insurance coverage; the possible disruption of our operations due to terrorist activities and armed conflict, including as a result of the disruption of the operations of certain regulatory authorities and of certain of our suppliers, collaborative partners, licensees, clinical trial sites, distributors and customers; and other factors described in our filings with the U.S. Securities and Exchange Commission. The statements in this press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Investor Contact
Mike Moyer, Managing Director
LifeSci Advisors
+1-617-308-4306
mmoyer@lifesciadvisors.com