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): December 26, 2023

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 December 26, 2023, Protalix BioTherapeutics, Inc. (the "Company") issued a press release containing a copy of a letter that the Company released to its stockholders. 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
99.1	Press Release dated December 26, 2023
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: December 26, 2023

PROTALIX BIOTHERAPEUTICS, INC.

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

Exhibit 99.1

Protalix BioTherapeutics Issues 2024 Letter to Stockholders

CARMIEL, Israel, December 26, 2023 /PRNewswire/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 the following letter from its President and Chief Executive Officer, Dror Bashan, to its stockholders.

December 26, 2023

Dear Protalix Stockholders,

As we approach the close of a transitional year for our company, I want to take a moment to reflect on our recent accomplishments…accomplishments that are shaping our path going forward. Elfabrio®, our second development candidate produced through our proprietary ProCellEx® plant cell-based protein expression system, was approved for the treatment of adult patients with Fabry disease by both the U.S. Food and Drug Administration and the European Medicines Agency. Approval of Elfabrio marks a significant milestone for our company and, more importantly, brings a new therapeutic option to patients with unmet needs. This achievement is a testament to the tireless efforts of our talented and professional team, and we take great pride in sharing this success with you, our dedicated stockholders.

As Elfabrio has moved from the development stage to being a commercial product, we are taking steps we believe will strengthen our internal operations and improve our production capabilities for two commercial products. We are confident that as the commercialization of Elfabrio continues to develop, it will enable us to improve our capital structure.

Our commercial partner, Chiesi Global Rare Diseases, played a pivotal role in our journey, and I extend my gratitude to Giacomo Chiesi and the entire Chiesi team. Their support has been instrumental in our combined success, and we look forward to further strengthening our relationship in the years to come. Since the approval, Chiesi has launched Elfabrio in the United States, the European Union and the United Kingdom, strategically positioning Elfabrio for success in those markets. Protalix is dedicated to being a valuable resource to Chiesi and facilitating Chiesi's commercial efforts.

We are continuing to make progress on our pipeline programs. We have finished the seventh cohort in the phase I clinical trial of PRX-115, our recombinant PEGylated uricase (urate oxidase) under development for the potential treatment of severe gout. At this time, 56 patients have been dosed in this trial and we anticipate completing the trial in the second quarter of 2024. Progress is also being made in the preclinical development of PRX-119, our plant cell-expressed PEGylated recombinant human DNase I product candidate which we are designing to elongate half-life in the circulation for NETs-related diseases. We look forward to updating you as we advance in the development of these and other product candidates, and as we begin to turn our focus to building a sustainable portfolio of treatments for rare diseases.

I also want to take a moment to acknowledge the challenges our community continues to face given the current situation in Israel. Our hearts are with all those who have been affected so profoundly, including our colleagues, partners and the broader community. We deeply appreciate the impact of these events on both a personal and professional level, and we continue to extend our support to everyone navigating these difficult times.

Looking ahead, the future of Protalix is filled with promise and potential. As we continue to innovate and strengthen our operations, I am confident that our company can deliver impactful solutions for the benefit of patients in need. Our commitment to excellence, coupled with the passion of our team, positions us well for continued growth and success.

In closing, I want to express my sincere appreciation for our employees and our Board of Directors for their ongoing dedication to our mission. I also want to thank you, our stockholders, for your continued confidence and trust in our vision. As we navigate the exciting journey ahead, I am optimistic about Protalix's future and the positive impact we can collectively make in the lives of patients and the broader healthcare community.

Thank you for your continued support. I hope you enjoy the holidays and have a happy new year.

Sincerely,

Dror Bashan, President & Chief Executive Officer

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 severe 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: risks related to the commercialization of Elfabrio, our approved product for the treatment of adult patients with Fabry disease; risks relating to Elfabrio's market acceptance, competition, reimbursement and regulatory actions, including as a result of the boxed warning contained in the FDA approval received for the product; risks related to our commercialization partner's ability to obtain and maintain reimbursement for Elfabrio, and the extent to which patient assistance programs and co-pay programs are utilized; the possible disruption of our operations due to the war declared by Israel's security cabinet against the Hamas terrorist organization located in the Gaza Strip, the military campaign against the Hezbollah and other 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; the likelihood that the FDA, EMA or other applicable health regulatory authorities will approve an alternative dosing regimen for Elfabrio; risks related to the regulatory approval and commercial success of our other product and product candidates, if approved; failure or delay in the commencement or completion of our preclinical studies 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

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; delays in the approval or potential rejection of any applications we file with the FDA, EMA or other health regulatory authorities for our other product candidates, and other risks relating to the review process; risks associated with the novel coronavirus disease, or COVID-19, outbreak and variants, which may adversely impact our business, preclinical studies and clinical trials; risks associated with global conditions and developments such as supply chain challenges, the inflationary environment and tight labor market, and instability in the banking industry, which may adversely impact our business, operations and ability to raise additional financing if and as required and on terms acceptable to us; risks related to any transactions we may effect in the public or private equity markets to raise capital to finance future research and development activities, general and administrative expenses and working capital; risks relating to our evaluation and pursuit of strategic partnerships; the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy and that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks relating to our ability to manage our relationship with our collaborators, distributors or partners, including, but not limited to, Pfizer and Chiesi; risks related to the amount and sufficiency of our cash and cash equivalents; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; risks relating to changes to interim, topline or preliminary data from clinical trials that we announce or publish; risks relating to the compliance by Fiocruz with its purchase obligations under our supply and technology transfer agreement, which may have a material adverse effect on us and may also result in the termination of such agreement; risk of significant lawsuits, including stockholder litigation, which is common in the life sciences sector; 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; risks related to our supply of drug products to Pfizer; potential product liability risks, and risks of securing adequate levels of related insurance coverage; the possibility of infringing a third-party's patents or other intellectual property rights and the uncertainty of obtaining patents covering our products and processes and successfully enforcing our intellectual property rights against third-parties; risks relating to changes in healthcare laws, rules and regulations in the United States or elsewhere; 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
Chuck Padala, Managing Director
LifeSci Advisors
646-627-8390
chuck@lifesciadvisors.com

Source: Protalix BioTherapeutics, Inc.