
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 30, 2021

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

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 June 30, 2021, Protalix BioTherapeutics, Inc., a Delaware corporation (the “Company”), participated in a fireside chat discussion hosted by Zacks Investment Research’s John Vandermosten. Dror Bashan, the Company’s President and Chief Executive Officer and Eyal Rubin, the Company’s Chief Financial Officer represented the Company in the chat. A recording of the chat is available on the Investors page of the Company’s website under the Events Calendar tab. The recording is accessible under “Supporting Materials” on the Event Details page for the fireside chat. The information contained on the website is not included as a part of, or incorporated by reference into, this 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.

Forward Looking Statements

To the extent that statements made in the fireside chat 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 timing and progress of the preparation of a Biologics License Application (“BLA”) resubmission addressing the Complete Response Letter (“CRL”) we received from the U.S. Food and Drug Administration (the “FDA”) on April 27, 2021; risks related to the timing, progress and likelihood of final approval by the FDA of a BLA resubmission for pegunigalsidase alfa (“PRX-102”) and, if approved, whether the use of PRX-102 will be commercially successful; the risk that the FDA, the European Medicines Agency or other foreign regulatory authorities may not accept or approve a marketing application we file for any of our other product candidates; 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 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 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 have undesirable side effects or other unexpected characteristics; risks associated with the novel coronavirus disease, or COVID-19, outbreak, which may adversely impact our business, preclinical studies and clinical trials; 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 related to our ability to maintain and manage our relationship with our collaborators, distributors or partners; 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; 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; 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 made in the fireside chat are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

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: June 30, 2021

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan

Name: Dror Bashan

Title: President and Chief Executive Officer
