
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 30, 2020

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 Snunit Street
Science Park, POB 455
Carmiel, Israel
(Address of principal executive offices)

2161401
(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 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 30, 2020, Protalix BioTherapeutics, Inc. (the “Company”) issued released a letter to its shareholders discussing recent corporate developments. A copy of the shareholder letter 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.

Forward Looking Statements

To the extent that statements in this Current Report, including Exhibit 99.1, 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,” “plan,” “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 our preclinical and clinical trials which may be caused by several factors, including: risks that the U.S. Food and Drug Administration (“FDA”) will not accept an application for accelerated approval of PRX-102 with the data generated to date or will request additional data or other conditions of our submission of any application for accelerated approval of PRX-102; 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 slower than expected rates of patient recruitment; risks associated with the novel coronavirus disease (COVID-19) outbreak, which may adversely impact our business, preclinical studies and 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; risks related to our ability to maintain and manage our relationship with Chiesi Farmaceutici and any other collaborator, distributor or partner; risks related to the amount of our future revenues and expenditures; the risk that despite the FDA’s grant of fast track designation for PRX-102, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA’s ability to withdraw the fast track designation at any time; 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 Current Report, including Exhibit 99.1, 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

99.1	Press release dated December 30, 2020
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 30, 2020

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan

Name: Dror Bashan

Title: President and Chief Executive Officer



December 30, 2020

Dear Protalix shareholders,

As we look forward to 2021 with great anticipation, I want to take a moment to reflect on our transformational accomplishments this past year, which has been unlike any we could have imagined. Together with our development and commercialization partner, Chiesi Global Rare Diseases, we submitted to the U.S. Food and Drug Administration (FDA) a Biologics License Application (BLA) for PRX-102 for the treatment of adult patients with Fabry disease, bringing us one step closer to the anticipated commercialization of this important treatment option. We also solidified our financial foundation and advanced our pipeline of candidates utilizing ProCellEx®, our proprietary protein expression system platform technology. At the same time, we continued to seek multiple collaborative partnerships to complement our core platform. Despite the many external challenges we faced this year, our team has been committed to accomplishing our goals and remained focused, and we persevered to position us for another year of value-adding milestones and transformational catalysts.

Advancing PRX-102 (pegunigalsidase alfa) for the treatment of Fabry Disease

Following the successful outcome of our Phase I/II clinical study of PRX-102, in May 2020, we, together with Chiesi, submitted the PRX-102 BLA to the FDA. The FDA accepted the filing under its Accelerated Approval pathway and granted Priority Review designation to PRX-102. The action date under the Prescription Drug User Fee Act (PDUFA) for the BLA has been updated to April 27, 2021.

Fabry disease represents a tremendous opportunity in a multi-billion dollar market ready for a potential better treatment option. We believe PRX-102, if approved, will meaningfully improve the quality of life for many Fabry patients and, together with Chiesi, we are preparing for the anticipated commercial launch.

Our PRX-102 phase III development program consists of three studies: the BRIDGE study; the BRIGHT study; and the BALANCE study. The BRIDGE and BRIGHT studies have been completed. Topline results of the data generated in the BRIDGE Study, which were released in May this year, showed substantial improvement in renal function, as measured by mean annualized estimated Glomerular Filtration Rate (eGFR slope), and an amelioration of the course of disease in both male and female Fabry patients who were switched from agalsidase alfa to PRX-102. Agalsidase alfa is marketed by Takeda Pharmaceutical Company Limited (Shire Plc) as Replagal®. Earlier today, we announced final results from our BRIDGE study, and we anticipate an announcement of the topline data from our BRIGHT study in the first quarter of 2021. We expect interim results from our BALANCE study in the first half of 2021.

We look forward to commercializing PRX-102 assuming the anticipated approval of the BLA in the second half of 2021.

Partnerships and Collaborations

This year, we continued expanding our relationships with other companies to leverage our pipeline through strong partnerships and collaborations.

In July 2020 we entered into a non-binding term sheet with SarcoMed USA Inc. The arrangement, if consummated, will relate to the development and commercialization of PRX-110 (alidornase alfa) for the treatment of pulmonary sarcoidosis and related diseases. We expect to be able to provide an update regarding SarcoMed USA in the next few weeks.

Earlier in the year, in March 2020, we announced an agreement with Kirin Holdings Company, Limited (Kirin) to conduct a feasibility study to evaluate production of a novel complex protein utilizing ProCellEx. We received a non-refundable payment of \$1.0 million and Kirin will provide research funding to conduct cell-line engineering and protein expression studies on the target protein.

Solid Financial Balance Sheet Supporting Corporate Strategy

We raised approximately \$44 million in March 2020 from the sale of common stock and warrants in a private placement to certain existing and new institutional and other accredited investors.

Subsequent to the completion of the private placement, we established an at-the-market (ATM) offering through Bank of America Securities Inc. through which we have the ability to raise up to \$30 million. This transaction signifies the quality of the banking

counterparties that were eager to work with us in this process and indicative of the growing interest in Protalix from institutional investors.

Enhanced Management Team

We continued adding to the senior executive management team with the appointment of Yael Hayon, Ph.D. as Vice President, Research and Development. Dr. Hayon is an important addition to the team as we advance our pipeline, bringing to the company over a decade of pharmaceutical research and development experience in both the scientific operations and administrative functions.

Looking Forward

We believe we are well positioned for success with an anticipated commercial product launch planned in a multi-billion dollar target market, a solid financial base to support growth and a pipeline of potential opportunities. We are excited to welcome 2021 and look forward to a bright future as a company. I thank our employees for their tireless efforts to get us to this point, as well as the physicians and patients who have participated and are participating in our trials.

Finally, we would like to thank you, our shareholders, for your support and we look forward to sharing our future successes with you.

Sincerely,

A handwritten signature in blue ink, appearing to be 'D. Bashan', is positioned above the typed name.

Dror Bashan, President & Chief Executive Officer, Director
Protalix Biotherapeutics, Inc.
