

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): August 30, 2019 (August 26, 2019)

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)

20100
(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))

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.

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

Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On August 26, 2019, Protalix BioTherapeutics, Inc. (the “Company”) received a deficiency letter from NYSE American LLC (the “NYSE American”) stating that the Company is not in compliance with the continued listing standards as set forth in Section 1003(a)(i) – (iii) of the NYSE American Company Guide (the “Company Guide”) as it has reported a stockholders’ equity deficiency as of June 30, 2019 and net losses in its five most recent fiscal years ended December 31, 2018.

The letter has no immediate effect on the listing of the Company’s common stock on the NYSE American. The Company’s common stock will trade on the NYSE American while it regains compliance with the continued listing standards.

Consistent with the rules set forth in the Company Guide, the Company intends to submit a detailed plan of compliance advising the NYSE American of the actions the Company has taken, or plans to take, that would bring it into compliance with the continued listing standards within 18 months of receipt of the letter.

The Company issued a press release on the same day of this report announcing that it had received the Deficiency Letter. A copy of the press release is filed as Exhibit 99.1 to this Current Report.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

[99.1 Press release dated August 30, 2019.](#)

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: August 30, 2019

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan

Name: Dror Bashan

Title: President and Chief Executive Officer

Protalix BioTherapeutics Receives Listing Deficiency Letter from NYSE American

CARMIEL, Israel, August 30, 2019 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins including a late-stage clinical product expressed through its proprietary plant cell-based expression system, ProCellEx[®], today announced that it received a deficiency letter from NYSE American LLC (the "NYSE American") stating that the Company is not in compliance with the continued listing standards as set forth in Section 1003(a)(i) – (iii) of the NYSE American Company Guide (the "Company Guide") as it has reported a stockholders' equity deficiency as of June 30, 2019 and net losses in its five most recent fiscal years ended December 31, 2018.

The letter has no immediate effect on the listing of the Company's common stock on the NYSE American. The Company's common stock will trade on the NYSE American while it regains compliance with the continued listing standards.

Consistent with the rules set forth in the Company Guide, the Company intends to submit a detailed plan of compliance advising the NYSE American of the actions the Company has taken, or plans to take, that would bring it into compliance with the continued listing standards within 18 months of receipt of the letter.

"The new management team leading Protalix continues to review the capital structure very carefully and is working diligently to address the NYSE American's requirements," said Dror Bashan, Protalix's President and Chief Executive Officer. "Protalix is evaluating and pursuing strategic alternatives to maximize shareholder value through financing and partnerships."

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's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (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 includes the following product candidates: pegunigalsidase alfa, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease, which is currently in a Phase 3 clinical trial (BALANCE study); and OPRX-106, an orally delivered anti-inflammatory treatment and alidornase alfa for the treatment of Cystic Fibrosis, both in Phase 2 clinical trials. 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.

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,” “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: risks related to our ability to identify and complete strategic alternatives on attractive terms or at all within the time period required to regain compliance with the continued listing standards of the NYSE American; risks related to our ability to continue as a going concern absent a refinancing or restructuring; risks related to any transactions we may effect in the public or private equity markets to raise capital to finance future activities; 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 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; risks related to our ability to continue as a going concern absent access to sources of capital we will need to finance future research and development activities, general and administrative expenses and working capital; risks related to any capital raising 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; slower than expected rates of patient recruitment; 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 lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of our product candidates will not support our claims of superiority, 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 and sufficiency of our cash and cash equivalents; risks related to the ultimate purchase by Fundação Oswaldo Cruz of alfataliglicerase pursuant to the stated purchase intentions of the Brazilian Ministry of Health of the stated amounts, if at all; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase generally; risks related to our commercialization efforts for alfataliglicerase in Brazil; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the amount of our future revenues, operations and expenditures; the risk that despite the FDA’s grant of fast track designation for pegunigalsidase alfa for the treatment of Fabry disease, 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; 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; 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; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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 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.

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