
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 29, 2022

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 1.01 Entry into a Material Definitive Agreement

On August 29, 2022, Protalix BioTherapeutics, Inc., a Delaware corporation (the “Company”), entered into a Fill/Finish Agreement (the “Agreement”) and a Letter Agreement (the “Letter Agreement”), in each case, with Chiesi Farmaceutici S.p.A. (“Chiesi”). Chiesi serves as the Company’s commercialization partner for PRX-102, the Company’s investigational new drug product under development for the potential treatment of Fabry disease, pursuant to that certain Exclusive License and Supply Agreement dated October 17, 2017 and that certain Exclusive U.S. License and Supply Agreement dated July 23, 2018, in each case, by and between the Company and Chiesi (such agreements, collectively, the “License Agreements”).

Under the Agreement, the Company agreed to supply Chiesi with drug substance for PRX-102 and, following relevant technology and technical information transfer activities, Chiesi has agreed, among other things, to provide the Company with commercial fill/finish services for PRX-102, including to support the anticipated global launch of PRX-102.

The Agreement shall continue in force until December 31, 2025, unless terminated earlier in accordance with the terms of the Agreement. The Company and Chiesi may extend the term of the Agreement for an additional period of seven years upon mutual written agreement prior to expiration of the initial term.

The Agreement also contains provisions relating to compliance with current manufacturing practices and applicable laws and regulations, and to intellectual property, indemnification, confidentiality, representations and warranties and the impact of certain events under the Agreement on the obligations of the Company and Chiesi under the License Agreements, and other customary matters for an agreement of this kind.

The Letter Agreement modifies the obligations of the Company and Chiesi under the License Agreements with respect to, among other things, the evaluation, selection and establishment of an initial alternate source of commercial fill/finish services for PRX-102. In addition, the Letter Agreement amends certain provisions of the License Agreements to reflect the appointment of Chiesi as a supplier of commercial fill/finish services and the potential establishment of an initial alternate source of commercial fill/finish services.

The foregoing is only a summary description of the material terms of the Agreement and the Letter Agreement, does not purport to be a complete description of the terms of the Agreement or the Letter Agreement and is qualified in its entirety by reference to the Agreement and the Letter Agreement, respectively, redacted versions of which will be filed as exhibits to the Company’s Quarterly Report on Form 10-Q for the quarter ending September 30, 2022.

Item 9.01 Financial Statements and Exhibits

<u>Exhibit No.</u>	<u>Description</u>
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: September 1, 2022

PROTALIX BIOTHERAPEUTICS, INC.

By: /s/ Dror Bashan

Name: Dror Bashan

Title: President and Chief Executive Officer
