

GENEREX BIOTECHNOLOGY CORP

Form 8-K

November 26, 2018

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): November 20, 2017

GENEREX BIOTECHNOLOGY CORPORATION

(Exact name of registrant as specified in its charter)

Delaware

000-29169

98-0178636

(State or other jurisdiction of

(Commission File Number) (I.R.S Employer Identification No.)

incorporation)

10102 USA Today Way, Miramar, Florida 33025

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (416) 364-2551

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:

Written communications 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))

1

Item 1.01. Entry a Material Definitive Agreement

On November 20, 2018, , the Company's wholly owned subsidiary, Antigen Express, Inc. ("Antigen") entered into a Clinical Trial Agreement with NSABP Foundation, Inc. ("NSABP"). Pursuant to the Clinical Trial Agreement, NSABP will conduct a Phase II Study to evaluate efficacy of administering Merck Sharpe & Dhome's ("Merck") Keytruda® (pembrolizumab) in combination with Antigen's AE37 cancer vaccine for the treatment of metastatic triple negative breast cancer. While Merck is not a party to the Clinical Trail Agreement, Merck is expected to provide Keytruda® for the study pursuant to the Clinical Trial Collaboration and Supply Agreement between Antigen and Merck.

An initial payment from Generex in the amount of \$340,000 is due by December 20, 2018. If the study runs the full anticipated term, Generex will be responsible for an aggregate \$2,118,461.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

The list of exhibits called for by this Item is incorporated by reference to the Exhibit Index filed with this report.

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 thereunto duly authorized.

GENEREX BIOTECHNOLOGY CORPORATION.

Date: November 26, 2018 /s/ Joseph Moscato
Joseph Mopscato
President and CEO

Exhibit Index

Exhibit No. Description

10.1 Clinical Trial Agreement between NSABP Foundation, Inc. and Antigen Express, Inc.

4

