UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

DIVISION OF
CORPORATION FINANCE

June 5, 2020

Joseph Moscato
President and Chief Executive Officer
GENEREX BIOTECHNOLOGY CORP
10102 USA Today Way
Miramar, FL 33025

Re: GENEREX BIOTECHNOLOGY CORP
Form 10-K for the Fiscal Year Ended July 31, 2019
Filed November 12, 2019
File No. 000-25169

Dear Mr. Moscato:

We have reviewed your April 30, 2020 response to our comment letter and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to these comments within ten business days by providing the requested information or advise us as soon as possible when you will respond. If you do not believe our comments apply to your facts and circumstances, please tell us why in your response.

After reviewing your response to these comments, we may have additional comments. Unless we note otherwise, our references to prior comments are to comments in our March 25, 2020 letter.

Form 10-K for the Fiscal Year Ended July 31, 2019

Item 101. Business, page 4

1. Refer to your response to comment 7. Please confirm that you will clarify in the filing all significant research and development milestone dates for each of your agreements, including the milestones noted in your response. In this respect, your response only appears to address the Merck/NSABP agreement. Please revise your response to include the dates of any significant milestone for any of your other agreements or confirm that there are none.

Management's Discussion and Analysis
Results of Operations, page 70

2. With regards to your response to comment 2, please address the following:

- Confirm that you will include a table relating to the breakdown of research and development costs in future filings. In this respect, consider revising the table provided to separately present each significant product candidate, to the extent that the research and developments costs are known. For example, you could present AE37 in combination with Keytruda, ECMH Rectal solution for Ulcerative Colitis, and Express II Syphilis Treponemal Assay as separate line items. Research and development costs for insignificant product candidates could be included in a separate line item and any unallocated costs could be separately presented as well.
- Clarify to us your statements with respect to the Excellagen product that "limited funding is required to development the project further to create a viable "room temperature" product" and "Excellasome requires substantial funding and will not continue without such funding" as those two statements appear to be contradictory.
- You state that it is expected that the costs of development of a vaccine of the SARS-CoV-2 virus will be borne by the U.S. and foreign agencies. You also state that you will not pursue those projects. Please reconcile those statements with your discussion of your plan to make a targeted vaccine that produces a complete immune response that neutralizes the virus. Provide us proposed disclosure to be provided in future filings regarding your role in developing a vaccine or work related to COVID-19.
- Please clarify to us and in your proposed disclosure how you intend to propose a pivotal clinical trial in the fall of 2020 and begin delivery of up to 100 million doses of vaccine starting in the fall of 2020.

Consolidated Statements of Operations and Comprehensive (Loss) Income, page 82

3. Refer to your response to comment 3. Please note that ASC 805-30-35 requires you to remeasure the fair value of your contingent consideration each period. Please confirm that the changes in the fair value have been immaterial for the periods presented, including the six months ended January 31, 2020, and revise your policy in future filings.

Consolidated Statements of Changes in Stockholders' Equity, page 83

4. Refer to the company's response to comment 4 and address the following:
   - Please clarify in future filings on page 96 and throughout as applicable your accounting treatment for the Olaregen acquisition. For example, clarify that the company did not issue the 4 million shares in connection with the acquisition of the preferred stock of Olaregen and your accounting treatment as a capital contribution for that issuance.
   - With respect to the 8,400,000 shares delivered in the Veneto acquisition, please clarify in future filings that the company did not issue the shares and your accounting treatment as a capital contribution for that issuance.
   - Refer to your disclosure on page 104 of the 10-K whereas you discuss recording a derivative liability for downside protection relating to the 8,400,000 shares issued. Please provide us an analysis of how the downside protection was structured, how

you determined the amount of the derivative, and the accounting GAAP literature supporting your accounting treatment. Specifically tell us if the company or the Trust is responsible for paying the downside protection.

- With respect to the 1,953,257 issuances of common stock for conversion of debt, tell us how the $13,431,703 charge to APIC was determined. Specifically tell us how many shares were issued by the Generex Trust, the date of the transaction, and the share price on the date of the transaction. Reconcile for us the per share ratio of the conversion of debt for each share issued, including any shares issued by the Generex Trust with the trading price of the stock on the date of issuance. Clarify in future filings that $13,431,703 of the $18,4040,731 charge to APIC was a result of contributions by the Generex Trust. Clarify the nature of the Trust and that the Trust is not consolidated with your financial statements.
- Please tell us if other shares were issued by other than the company, in other transactions not discussed herein, the circumstances and accounting thereof and revise to clarify throughout the filing.
- Reference is made to the $13,929,129 conversion of debt to equity and the disclosure in your April 30, 2019 Form 10-Q. Tell us and address the following in future filings as applicable:
  - if the $13,929,129 relates to the 8,400,000 Generex shares issued by the Trust and the 5,500,000 subsidiary shares and who contributed the 5,500,000 subsidiary shares and the accounting treatment thereof.
  - why you classify the transaction as an extinguishment of debt-Veneto in the Statements of Stockholders' Equity in the Form 10-Q for the period ended April 30, 2019 and a conversion of debt to equity in the Statements of Stockholders' Equity in the Form 10-K.
  - if you recorded any gain or loss on the extinguishment of debt and the basis for your accounting and where that amount is disclosed
  - why recording the conversion rate at $2.50 per share as discussed on page 37 of the Form 10-Q is appropriate when the trading value of the common stock was significantly below the $2.50 per share on the date of the transaction
  - the journal entries recorded in the transaction for the extinguishment/conversion of debt, which would include the derivative liability recorded for the downside protection noted. Also provide the accounting basis for the entries recorded
  - a recalculation of the change in the derivative liability for the downside protection. Please reconcile the change in the downside protection to the trading value of your stock at the end of the period.
- Reference is made to the issuance of warrants and net amount recorded in APIC of $5,592,244 which based on your response represents the accumulated value of warrants issued in the Acquisition of NGIO and subsequent changes in fair value related to those warrants. You reference Note 13 in your response relating to the $5,592,244. Please address the following:
  - Clarify if you meant the acquisition of NGDx instead of NGIO.
  - Reconcile for us the $5,592,244 net amount recorded to APIC to the $9,032,435

gross amount recorded to APIC upon issuance of the warrants as disclosed on page 101 of your 10-K.

- Tell us why changes in the fair value of the warrants were being made and why the changes were going through APIC.

Revenue, page 86

5. We acknowledge your response to comment 5. Please confirm that you will provide the disclosures required by ASC 606 in future filings for disaggregated revenue, significant judgments and changes in judgments, and contract balances as requested in our comment relating to your new revenue streams. In addition, please confirm that you will quantify in Management's Discussion and Analysis each significant factor that resulted in significant changes in revenue and the extent to which the changes relate to price vs volume.

Notes to the Consolidated Financial Statements
Note 2- Summary of Significant Accounting Policies Research and Development Costs, page 88

6. We acknowledge your response to comment 6 and the proposed additional disclosure. As you appear to indicate that each agreement is a material agreement, please refer to Rule 601(b)(10) of Regulation S-K and address the following:
   - We believe the significant terms of each material agreement are required to be presented in the filing such as the rights and obligations of each party, including any significant milestone payments paid/received to date and aggregate potential milestones and the triggering factors thereof, the royalty percentages or a range, profit sharing, and termination clauses. Disclosure in the 8-K and exhibits thereof is not sufficient. Please note that reference to royalties in the double-digits, such as the disclosure for the Shenzhen agreement, is not sufficient as it is not within a 10 percentage point range. Please provide proposed disclosure to be included in future periodic reports, including the next Form 10-Q. To the extent that any of the above terms do not apply to any of your material agreements, please specifically state that fact in your response.
   - The Exhibit Index on page 132 does not appear to comply with Item 15 to the Form 10-K and Item 601 of Regulation S-K. Please confirm that you will revise your periodic reports in future filings to include the Exhibit list as required.

Note 12 - Goodwill and Intangible Assets, page 100

7. Refer to your response to comment 8. The goodwill remaining on the balance sheet represents 60% of the original goodwill recorded, which appears to be attributed to the MSO business. As the MSO business model has changed substantially since the acquisition, tell us why the goodwill is not impaired at each of the balance sheet dates.

Note 13 - Acquisitions
Regentys and Olaregen, page 106

8. Refer to your response to comment 10 and address the following:
   - You state that the primary value for the IPR&D for Olaregen was attributed to Excellagen which based on page 40 of your January 31, 2020 Form 10-Q obtained FDA 510K clearance on October 3, 2013 for 17 indications. Tell us why you believe Excellagen was not commercially viable upon acquisition.
   - You state in response to comment 2 that no additional resources are currently needed for Excellagen as the project has FDA 510K approval with active sales. In addition, we note that you recently launched Excellagen and based on page 46 of the 10-Q appear to have begun recording sales in the three months ended October 31, 2019.
     - Tell us why the assets acquired relating to Excellagen were not recorded as an amortizable intangible product right asset.
     - If you continue to believe that the assets should be accounted for as IPR&D, please tell us what assets were acquired that are used in R&D activities in light of your discussion in response to comment two which appears to indicate that you are not currently undergoing R&D activities relating to Excellagen and your statement in comment 10 that Excellagen requires no future research and development.
     - If you are not currently undergoing R&D activities, clarify why you believe a write-off of the IPR&D was not required.
   - You state that you used the cost accumulation method to determine the value of the Regentys IPR&D.
     - Please tell us how the cost accumulation method is appropriate to determine the fair value.
     - Please help us understand the nature of the non-competes, including the term of the agreement.
     - Clarify why the non-competes are considered IPR&D.
     - Tell us why amortization of any non-compete agreements did not begin immediately.
   - Tell us why the relief from royalty method is an appropriate methodology to value the IPR&D acquired in the Olaregen acquisition.
   - Clarify your reference to the use of the income approach and multiple methods for Olaregen and in what circumstances each method was used. If you combined methodologies in your valuation, clarify how that was done and why you believe it was appropriate.
   - At a minimum, please disclose in future filings the efforts to complete all of your significant in-process research and development projects and the impact of any delays on your expected investment return, results of operations and financial condition. In this respect, please enhance the response to the last bullet of comment 10 to encompass more specific information relating to your efforts to complete the in-process research and development.

Item 9A. Controls and Procedures, page 114

9. Please amend the 10-K to include the revised disclosures included in your response to comment 13 for your disclosure controls and procedures and internal controls. In this respect, please revise your proposed disclosure for risk factors regarding your internal controls to delete reference to disclosure controls and procedures in the second paragraph of the proposed disclosure. Include updated management certifications as required.

You may contact Mary Mast at (202) 551-3613 or Dan Gordon at (202) 551-3486 with any questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences