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

DIVISION OF
CORPORATION FINANCE

March 25, 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 limited our review of your filing to the financial statements and related disclosures 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.

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

Management's Discussion and Analysis
Financial Condition, Liquidity and Resources
Sources of Liquidity, page 70

1. You state that your July 31, 2019 cash position was not sufficient for 12 months of operations and that anticipated revenues associated with the Veneto acquisition are expected to dramatically alter the cash flow landscape. Given the litigation with Veneto and the uncertainty relating to the assets acquired, tell us the basis for the company's assertions.

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

2. For each significant key research and development project, provide the following to be included in future filings:

- the costs incurred during each period presented, reconciled to your research and development on your Statements of Operations
- the nature of efforts and steps necessary to complete the project,
- reasons for significant increases or decreases in research and development from period to period,
- expected future increases or decreases in research and development,
- the risks and uncertainties associated with completing development,
- the extent and nature of additional resources that need to be obtained if current liquidity is not expected to be sufficient to complete the project, and
- your estimate of the date of completion of any future milestone such as completion of a development phase, date of filing an NDA with a regulatory agency, or approval from a regulatory agency.

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

3. The changes in fair value of contingent purchase consideration were $18,587,782 and $39,027,901 and $0 in the years ended July 31, 2019 and 2018 and three months ended October 31, 2019, respectively. Please tell us the amount of contingent consideration at each balance sheet date and the components thereof. Also tell us your consideration of separately presenting the contingent consideration on the face of the balance sheet. Clarify to us why there was no change in the fair value in the three months ended October 31, 2019 either to the contingent consideration outstanding at July 31, 2019 or the additional contingent consideration recorded in connection with the MediSource and Pantheon acquisitions as disclosed on page 22 of your October 31, 2019 10-Q.

Consolidated Statements of Changes in Stockholders' Equity, page 83

4. You state on pages 95 and 109 that in May 2019 you issued 4 million shares of common stock in exchange for 592,682 shares of Series A preferred stock of Olaregen. You also state on page 104 that in connection with the Amendment Agreement for the Veneto acquisition you delivered 8,400,000 shares on May 23, 2019. Please tell us where the issuance of shares is presented in the Statements of Changes in Stockholders' Equity.

   You issued 1,953,257 common stock for the issuance of common stock for conversion of debt and recorded $18,404,731 of additional paid-in-capital. Please provide us an analysis of the transactions, including how the amount recorded to additional paid-in capital was determined in light of your stock price at the time of the transactions. Also, please reconcile the transactions to the disclosure presented on page 83 and elsewhere in the filing, as applicable.

Revenue Recognition, page 86

5. You disclose several different types of revenue streams such as product sales, pharmacy prescriptions, laboratory services, and management services. Please revise to provide the following or tell us why additional disclosure is not required:

- disaggregated revenue recognized pursuant to ASC 606-10-50-5 and ASC 606-10-55-89 through 55-91, including disclosure relating to geographical regions if applicable,
- significant judgments and changes in judgments pursuant to ASC 606-10-50-17, including how variable consideration was determined for each significant revenue stream,
- contract balances pursuant to ASC 606-10-50-6 through 606-10-50-11, and
- additional disclosure in Management's Discussion and Analysis quantifying each significant factor that resulted in significant changes in revenue and the extent to which the change relates to price vs. volume. Refer to item 303(a)(3) of Regulation S-K.

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

6. You state on page 11 that you have entered into agreements with Merck and NSABP to conduct a Phase II trial to evaluate the safety and efficacy of AE37 in combination with KEYTRUDA. You also state that you are advancing AE37 for the treatment of prostate cancer through a licensing and research agreement with Shenzhen. For these agreements and any other agreements entered into subsequent to July 31, 2019, tell us the date of the agreements, the nature and significant terms of those agreements, including the rights and obligations of each party and any commitments and contingencies with respect to the agreements. Tell us your consideration of providing additional disclosure in the filing in accordance with ASC 450, 730, and 808; Items 101, 303, and 601 of Regulation S-K; and any other applicable guidance.

7. With respect to your historical business discussed on page 42 and elsewhere in your filing, clarify the dates in which you completed significant research and development milestones. Tell us your consideration of providing additional disclosure in the filing. For example, tell us when you completed the Phase IIb clinical trial of AE37 immunotherapeutic peptide vaccine with the Ii-Key technology in over 300 women with breast cancer.

Note 12- Goodwill and Intangible Assets, page 100

8. With respect to your acquisition of Veneto on October 3, 2018 we note the following:
   - You state on page 66 that you are currently in litigation with Veneto regarding the assets and business transferred, many of the contractual arrangements you assumed have been terminated, and you have had to rebuild the business relationships and the structure of the contractual relationships you took over from Veneto. You also state on page 45 that the MSO was built through relationships between physicians and the previous Veneto administration.

- You state on page 69 that the arbitration action alleges that Veneto never transferred the ownership rights in at least one pharmacy to NDS and that pharmacy was a necessary element in the operation of other assets transferred by Veneto.
- You state on page 94 that certain assets were never transferred due to regulatory impositions and that NuGenerex is not responsible for repayment of a loan on assets not transferred.
- You state on page 85 that in March 2019 you changed your business model to no longer utilize their existing pharmacies which resulted in you breaking your existing lease agreements with your pharmacies. In this respect we note your disclosure on page 95 which states that $292,681 of disposals pertain to Veneto and was mostly the result of your shift in business operations during March 2019.

You disclose on page 105 that you revalued the assets during the measurement period in accordance with ASC 805-10-25-14 and reduced goodwill accordingly. However your disclosure, as noted above, appears to imply that the assets recorded may need further consideration, including potentially an impairment for events occurring after the acquisition date such as the change in your business model. Please provide us your analysis regarding the valuation of the assets recorded in connection with the Veneto acquisition, including goodwill. Your analysis should at a minimum include the following:

- the nature of each significant asset acquired in the acquisition,
- the status of ownership and rights for each significant asset at the time of the acquisition and at your balance sheet date,
- how each asset was affected by your change in business model,
- how each asset was affected by any terminated contractual arrangements,
- the extent to which you have had to rebuild business relationships, including the network of physician partners in the MSO acquired from Veneto, and
- the effect of the ongoing litigation with Veneto

Note 13 - Acquisitions

Veneto, page 104

9. You appear to consolidate the assets acquired of Veneto. You state on page 45 the MSO acquired from Veneto is named Rapport Services, LLC (“Rapport”), which is a physician-owned limited liability company (or LLC) requiring an at-risk equity investment from physicians or physician groups that wish to participate in the network. The Rapport physician investors own 99% of Rapport, and Generex (through your wholly-owned subsidiary NuGenerex Distribution Solutions 2) owns 1% and serves as the managing director of the LLC. Please provide us with your analysis as to why consolidation is consistent with ASC 810. If Veneto is not considered a variable interest entity, please provide your assessment of consolidation under the entities controlled by contract in ASC 810-10-25-60.

Regentys and Olaregen, page 106

10. Please provide us the following with respect to the $2,459,000 of in-process research and development recorded in the Olaregen acquisition and $3,391,050 acquired in the Regentys acquisition:
    - the specific nature and fair value of each significant in-process research and development project acquired.
    - the completeness, complexity and uniqueness of the projects at the acquisition date.
    - the nature, timing and estimated costs of the efforts necessary to complete the projects, and the anticipated completion dates.
    - the risks and uncertainties associated with completing development on schedule, and consequences if it is not completed timely.
    - what appraisal method was used to value the projects.
    - the significant appraisal assumptions, such as:
        - the period in which material net cash inflows from significant projects are expected to commence;
        - material anticipated changes from historical pricing, margins and expense levels; and
        - the risk adjusted discount rate applied to the project's cash flows.
    - In periods subsequent to the purchase of significant in-process research and development, tell us the status of efforts to complete all of your significant in-process research and development projects, including those other than the assets acquired in the Olaregen and Regentys acquisitions, and the impact of any delays on your expected investment return, results of operations and financial condition.

Regentys, page 107

11. You state that you acquired a 51% interest in Regentys for total consideration of $15,000,000, which consisted of a $400,000 cash payment and a promissory note of $14,600,000. Please provide us the following:
    - a calculation of how the non-controlling interest of $9,870,762 was determined,
    - an analysis of the methodology and assumptions used as described on page 108 to determine the redeemable non-controlling interest of $4,073,898 were determined, and
    - how the fair value of the assets acquired of $907,833 equates to the amount of the assets disclosed in the table on page 107.

Olaregen, page 108

12. You state on pages 5 and 109 that in January 2019 you acquired a 51% interest in Olaregen for total consideration of $400,000 of cash and a note receivable of $11,472,664. You state on page 113 that your interest was increased to 62% in May 2019 upon acquisition of the Series A preferred stock in Olaregen in exchange for 4 million shares of your common stock plus the issuance of a $2 million promissory note. In August 2019, subsequent to your balance sheet date, your interest increased to 76%.

Please provide us the following:

- a calculation of how the non-controlling interest was determined,
- how the fair value of the assets acquired of $2,461,400 equates to the amount of the assets disclosed in the table on page 109, and
- how you are accounting for the additional interest purchased in May and August 2019.

Item 9A. Controls and Procedures, page 114

13. You state in your Management's Report on Internal Control Over Financial Reporting on page 115 that you have evaluated the effectiveness of your disclosure controls and procedures and concluded that your disclosure controls and procedures were not effective. Please present your assessment of the effectiveness of the disclosure controls and procedures under the subheading for "Evaluation of Disclosure Controls and Procedures" and a separate assessment relating to your assessment of internal controls over financial reporting under the Management's Report on Internal Control over Financial Reporting subheading. Refer to Items 307 and 308 of Regulation S-K. Please also revise your Risk Factor on page 42 to address your determination of effectiveness of the disclosure controls and procedures and internal control over financial reporting separately.

14. You refer to a restatement which was included in your Form 10-Q/A for the period ended January 31, 2019. In this respect, please tell us the basis for eliminating the intercompany revenue of $1,406,529 against the general and administrative expenses as noted on page 12 of the 10-Q/A.

In closing, we remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

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

Sincerely,

Division of Corporation Finance
Office of Life Sciences