



DIVISION OF
CORPORATION FINANCE

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

April 8, 2020

Joseph Moscato
Chief Executive Officer
NuGenerex Immuno-Oncology, Inc.
10102 USA Today Way
Miramar, FL 33025

**Re: NuGenerex Immuno-Oncology, Inc.
Registration Statement on Form 10-12G
Filed March 12, 2020
File No. 000-56153**

Dear Mr. Moscato:

We have reviewed your filing 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.

Registration Statement on Form 10-12G

AE37 – li-Key/HER2/neu Hybrid Immunotherapeutic Vaccine, page 4

1. We note your disclosure regarding certain clinical trials in this section. Please expand your disclosure to discuss specific trial results for your product candidate on which you intend to rely, including the duration of the trial, the number of subjects or patients in such trials, how the product candidate was administered, who conducted the trials, the dosage used, any serious adverse events experienced, the primary and secondary endpoints and whether they were met. Also, please be sure to identify the year or years when referenced trials were conducted or commenced.
2. With respect to your collaborative agreement with Merck and the NSABP, please disclose each parties' rights and obligations under the agreement, the duration of the agreement, the termination provisions and any payment provisions. Please also file the agreement as an exhibit or tell us why you believe it's not necessary.

3. With respect to your licensing and research agreement with Shenzhen, please disclose each parties' rights and obligations under the agreement, the duration of the agreement and the royalty term, the termination provisions, the aggregate future milestone payments to be received and the royalty rates. Please also file the agreement as an exhibit or tell us why you believe it's not necessary.
4. We note your disclosure that Shenzhen will be financing and conducting the Phase II trials in the European Union and Phase III trials globally for AE37 for prostate cancer and that you will retain rights to all clinical data for regulatory submissions and commercialization in the rest of the world outside China. Please disclose in which jurisdictions you intend to seek regulatory approval of AE37 for prostate cancer and how potentially conducting clinical trials outside of such jurisdictions might increase the length of time, the steps required or the cost of obtaining approval.

Item 1. Business, page 4

5. Please revise to clarify the current status and next steps for each of your product candidates, including the current stage of clinical development and for what indications, whether you or a third party will be conducting the clinical trials, the funding you will need, what steps remain to achieve regulatory approval and the planned timeline.
6. We note your disclosure on page 6 regarding pre-clinical work to support peptide vaccines for the treatment of melanoma. We also note disclosure on the Generex website regarding the development of a peptide vaccine for COVID-19 with EpiVax using the Nugenerex Ii-Key technology. Please tell us why you have not provided any disclosure about this vaccine in this section.
7. We note your disclosures on pages 11 and F-7 indicating that you will be a "separate" and "independent" company. Please revise to discuss the actions that you and your parent company, Generex will undertake to effectuate these plans and the relevant timing. Clarify what, if any relationship, you will have with Generex once these actions are complete.
8. We note your disclosure on page 8 that the initial IND for AE37 was filed in March 2006. Given that 14 years have passed and AE37 has not progressed past Phase II, please disclose what contributed to this delay in advancement of the product candidate and what has led to the recent activity.

Clinical Development Plans for Ii-Key Immunotherapeutic Peptides, page 5

9. Please name the major oncology research centers referenced in this section. If you have any agreements in place with these centers, please provide a summary of the material terms in this section and file the agreements as exhibits or tell us why you believe it's not necessary. It appears that the Ii-Key peptides are in the research and development phase and no clinical trials are currently contemplated. If that is the case, then please remove any reference to "clinical development plans."

Intellectual Property, page 5

10. Please disclose the expiration dates for each of your patents. Please also explain how you obtained a worldwide patent. We note your disclosure that some U.S. patents on the Li-key technology have expired. Please disclose whether the inability to extend the patent protection for these patents would have a material impact on your business and if so, what you intend to do should you not be successful in extending the patent coverage.

Competition, page 6

11. Please revise this section to provide support for your statement that you are a "major player" in the immuno-oncology field. In this regard, please revise to disclose, if true, that NGIO has never received regulatory approval for a product candidate or had commercial sales.

Government Regulation and Product Approval, page 8

12. We note your disclosure that the Physician's Investigational New Drug Application for the Phase 1 and Phase II trial of AE37 became effective in March 2006. Please revise to disclose who Physician's is and what their relationship is to you. We note your disclosure that the IND for the Phase II trial of AE37 for treatment of triple negative breast cancer became effective in December 2018. Please disclose who filed the IND.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations, page 10

13. You incurred research and development expenses of \$354,000 and \$234,317 during the years ended July 31, 2019 and 2018, respectively. Please revise your disclosure to describe the significant components of your research and development expenses, including the amount incurred during each period presented for each significant research program / project. In this respect, please clarify the reasons for significant increases or decreases in research and development from period to period and disclose any expected future increases or decreases.

Financial Condition, Liquidity and Resources, page 11

14. Please disclose the additional funding that you will need and how far in the development process of each product candidate you expect to get with this amount of funding.
15. We note your disclosure that you will no longer be able to rely on your former primary owner for necessary financing. However, you also state that you will rely primarily on Generex financing activities to fund your operations, development and other activities going forward. Please revise to clarify what you mean.
16. We note the reference to further clinical trials for A27 in this section, but there are no other references to this product candidate in the filing. Please revise or advise.

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Financial Statements, page F-1

17. Please revise to provide updated interim financial statements in accordance with Rule 8-08 of Regulation S-X.

Statement of Operations, page F-4

18. Please revise the line item "Sales" to clarify the nature of the revenue recorded.

Statements of Cash Flows, page F-6

19. The line item "Non-cash interest" on your statement of cash flows appears to be the accrued interest on your payable to the Henry J. Jackson Foundation. Please explain to us why you have presented this change as non-cash interest rather than increase in interest payable. Refer to ASC paragraphs 230-10-45-28 and 55-13.

Note 2- Summary of Significant Accounting Policies

Research and Development Costs, page F-8

20. You state on page 4 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.
21. You discuss on page 4 your research and development programs and you state on page 6 that you have had decades of experience in cancer immunotherapy. Clarify in the filing the dates in which you completed significant research and development milestones. For example, disclose when you completed the Phase IIb clinical trial of AE37 immunotherapeutic peptide vaccine with the li-Key technology in over 300 women with breast cancer.

Note 3- Commitments and Contingencies

Commitments, page F-9

22. You state that you were billed \$251,459 related to the CTA and incurred \$37,076 for work performed on clinical trials and as a result you have a balance of \$214,383 in other current assets. Clarify why the apparent net liability of the company relating to research and development expense is recorded as a current asset on your balance sheet.

Payable to Foundation, page F-10

23. You state on page F-10 that you entered into a clinical study agreement with a Henry J. Jackson Foundation for the clinical research and development of AE37 for the treatment of breast cancer. Please address the following:
- Disclose the significant terms of the clinical study agreement with the Henry J. Jackson Foundation or clarify that it has been terminated.
 - Disclose all significant terms of the Forbearance agreement.
 - Clarify which agreement may be terminated by the Foundation at its sole discretion.
 - Based on the disclosure on page F-10, it appears that the Payable to Foundation is a current liability. Please present a line item on the balance sheet for Total current liabilities consistent with ASC 210-10-45-5.

General

24. The cover page of your registration statement indicates that you qualify as an emerging growth company as defined in the JOBS Act. Please revise to address the following:
- Describe how and when a company may lose emerging growth company status;
 - Briefly describe the various exemptions that are available to you, such as an exemption from Section 404(b) of the Sarbanes-Oxley Act of 2002 and Section 14(a) and (b) of the Securities Exchange Act of 1934; and
 - State your election under Section 107(b) of the JOBS Act. If you have elected to opt out of the extended transition period for complying with new or revised accounting standards under Section 107(b), include a statement that the election is irrevocable. Conversely, if you have elected to avail yourself of the extended transition period for complying with new or revised accounting standards under Section 102(b)(1), provide a risk factor explaining that this election allows you to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. Also state that as a result of this election, your financial statements may not be comparable to companies that comply with public company effective dates.
25. Pursuant to Section 12(g)(1) of the Exchange Act, the Form 10 becomes effective automatically 60 days after the initial filing date. At that time, you will be subject to the reporting requirements of the Exchange Act. In addition, we will continue to review your filing until all of our comments have been addressed. If the review process has not been completed before the effectiveness date you should consider withdrawing the Form 10 registration statement to prevent it from becoming effective and, as applicable, file a new Form 10 registration at such time as you are able to respond to any remaining issues or comments.

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.

Joseph Moscato
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You may contact Eric Atallah at 202-551-3663 or Mary Mast at 202-551-3613 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmiento at 202-551-3798 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Jeffrey Wofford, Esq.