



DIVISION OF  
CORPORATION FINANCE

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

July 7, 2020

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

**Re: NuGenerex Immuno-Oncology, Inc.**  
**Amendment No. 1 to Registration Statement on Form 10-12G**  
**Filed June 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 and any amendment you may file in response to these comments, we may have additional comments.

Amendment No. 1 to Registration Statement on Form 10-12G

Introductory Comment, page 3

1. Please revise to clarify that the registration statement is effective and clarify your reporting status.

Item 1. Business

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

2. We note your disclosure in this section that you are currently developing AE37 for the treatment of cancer, including breast, bladder, prostate, and potentially other indications yet you state on page 13 that your Phase II clinical study using AE37 in combination with Keytruda for treatment of metastatic triple negative breast cancer is your only ongoing research and development project. Please revise or advise. In that regard, we note your response to our prior comment 4 that you are waiting to see

whether Shenzhen is successful in achieving positive results in the prostate cancer development program before determining how to proceed. Accordingly, please revise to disclose, if true, that you are not in the process of developing AE37 for prostate cancer as stated on page 4.

3. We note your response to our prior comments 2 and 3. Please revise to disclose the term and the termination provisions for each of the Merck, NSABP and Shenzhen agreements. Please also indicate whether the royalty term under the Shenzhen agreement is the same as the term of the agreement.
4. We note your response to our prior comment 8, but we do not see any disclosure concerning the failure to achieve the primary endpoint which prevented moving to a Phase III trial of AE37 in breast cancer. Please revise or advise.
5. We note your disclosure that the primary and secondary endpoints were met in the 2006 and 2007 trials for AE37. Please provide the data from the trials that support these statements and disclose how many subjects were in the 2006 trial.
6. We note your response to our prior comment 5 and reissue in part. Please revise to clarify the next steps for each of your product candidates, including how much funding you will need, what steps remain to achieve regulatory approval and the planned timeline.
7. Please revise the disclosure on page 5 to explain your basis for the statement that "funding for the development of a vaccine of SARS-CoV-2 virus is in advanced discussions and currently expected that the development costs will be borne by the U.S. and foreign government agencies."

#### Clinical Development Plans for Ii-Key Immunotherapeutic Peptides, page 6

8. We note your response to our prior comment 9. Please revise to provide the detail from your response that the discussions with the major oncology research centers are currently confidential, and the clinical trials are in the planning stages.

#### Competition, page 7

9. We note your response to our prior comment 11. Please revise to disclose, if true, that NGIO has never received regulatory approval for a product candidate or had commercial sales.

#### Note 2- Summary of Significant Accounting Policies

##### Research and Development Costs, page F-8

10. We note from your response and revised disclosures to comment 21 that you completed a Phase IIb trial of AE37 in combination with GM-CSF in November of 2019. Please address the following:
  - Clarify in the filing if the trial which was completed, as discussed on page 4, is the

same trial in which costs were incurred for AE37 in combination with Keytruda as disclosed on page 13 in which you incurred \$251,459 of costs. If not, please tell us where the costs for AE37 in combination with GM-CSF were recorded in your financial statements and revise your MD&A as necessary to discuss the costs incurred.

- You state on page 5 that "based on the results from the Phase II trial described above, NGIO entered into a Clinical Trial Collaboration and Supply Agreement" on June 28, 2017 with Merck. Since the Phase IIb trial was not completed until November of 2019. Please clarify in the filing what results you are referring to which resulted in the collaboration agreement with Merck in 2017.
11. We acknowledge your response and revised disclosures to comment 20. 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. For instance, it does not appear sufficient to omit disclosure of the termination provision in the agreement with Merck because you do not believe an accrual for a liability is warranted. Please revise your disclosure accordingly.

Note 3 - Commitments and Contingencies  
Payable to Foundation, page F-10

12. We note from your response and revised disclosures to comment 22 that effective August 1, 2015, you capitalized all outstanding unpaid interest on the outstanding balance. Please explain to us your basis for capitalizing the unpaid interest on this payable.

Exhibits

13. Please file an executed copy of Exhibit 10.3. In this regard, we note that it is unclear whether the counterparty signed the agreement.

Joseph Moscato  
NuGenerex Immuno-Oncology, Inc.  
July 7, 2020  
Page 4

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 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. Sarmento 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.