



DIVISION OF
CORPORATION FINANCE

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

January 10, 2021

Scott Carmer
Chief Executive Officer
NexImmune, Inc.
9119 Gaither Road
Gaithersburg, MD 20877

Re: NexImmune, Inc.
Draft Registration Statement on Form S-1
Submitted December 14, 2020
CIK No. 0001538210

Dear Mr. Carmer:

We have reviewed your draft registration statement 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 this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Draft Registration Statement on Form S-1

Overview, page 1

1. Please revise your disclosure on page 2 and on page 106 to provide the basis for your statement that your AIM-activated T cells are potent and can effectively distinguish between tumor cells and healthy cells. With reference to your disclosures on page 116, it appears that these two claims are based on your preclinical work.
2. We note your statements on pages 2 and 3 indicating that you have observed initial indicators of immunologic response in your Phase I/II trial of NEXI-001. Please balance your disclosure here and in the Business section to clarify, if true, that this portion of the trial is exploratory and that your claims are not supported by statistically significant trial results.

3. Please revise the Summary presentation, where appropriate, to address the following:
 - You plan to initially target a small patient population with your product candidates (page 35);
 - Only limited human study data is available for your AIM technology, and it remains not fully known as to what kind of cytokines may be released (page 18); and
 - The cost to manufacture your modified cell product candidates is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce (page 30).

Our Pipeline, page 4

4. With reference to your disclosures on pages 140-141, please revise the pipeline presentation to include all three development phases or advise. With respect to your ongoing NEXI-001 and NEXI-002 trials, tell us your basis for characterizing these as "Phase I/II" trials. We further note that it does not appear that the second or "Phase II" part of either trial has commenced because your disclosure in the second paragraph on page 124 indicates that you have yet not determined a "Phase II dose" for NEXI-001 and your disclosure on page 131 suggests that you have not commenced the expansion cohort for NEXI-002. As applicable, please also revise your Summary discussion of these trials on pages 2-3.
5. Please explain to us why your AIM ACT product candidate and AIM INJ product candidates should be highlighted in the pipeline table. To the extent that these programs are material to your business, please revise the Business section to explain these programs in greater detail, including a discussion of relevant pre-clinical work conducted or in process. In this regard, your disclosure in the Business section concerning the preclinical work should support the positioning of the arrows in your pipeline table.

Our Approach, page 5

6. We note your Summary disclosures claiming that you are a platform for "rapid" product development, you intend to "rapidly" advance NEXI-001 and NEXI-002 and that you will "accelerate" development of your AIM INJ modality. Please remove these statements or revise to provide appropriate balance and context so that these statements do not imply that you will be successful in developing and progressing your product candidates in a rapid or accelerated manner. In this regard, we note your page 24 disclosure that Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company, page 7

7. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

Risk Factors

Our bylaws to be effective upon the consummation of this offering designate certain courts..., page 76

8. Please revise your disclosure here and on page 185 to clarify that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and that there is uncertainty as to whether a court would enforce an exclusive forum provision for actions arising under the Securities Act.

Capitalization, page 84

9. Please revise to reflect the redeemable convertible preferred stock outside of permanent equity consistent with your interim balance sheet on page F-29.

Research and Development Expenses, page 94

10. We note that you have multiple drug candidates in varying stages of development and clinical testing and that research and development is a significant aspect of your business. Please revise to provide more detail for your research and development expenses for each period presented, including but not limited to by product candidate as well as by the nature of the expenses. To the extent that you do not track expenses by product candidate, please disclose as such.

Business

Our Approach, page 110

11. We note your statement that your current clinical trials of NEXI-001 and NEXI-002 utilize the HLA-A2 allele, which is expressed by more than 40% of the Caucasian population. Please revise to discuss in greater detail your plans for developing other HLA allele subtypes and how your exclusive use of the HLA-A2 allele in the present trials impacts, if at all, the regulatory pathway and timeline to commercialization. For instance, please discuss whether this limitation impacts your ability to advance these product candidates to a registrational trial or to obtain Breakthrough Therapy Designation. Also, discuss if a lack of data concerning other HLA allele subtypes and patient populations could impact the design of future clinical trials.

Our Strategy, page 111

12. We note your use of the term “significant unmet medical need”. This term may imply that your product candidates have been granted fast track designation or priority review by the FDA for products that treat certain serious unmet medical needs. Please revise or otherwise explain why you believe use of this term is appropriate.

AIM ACT T cell Characterization, page 116

13. We note your non-clinical comparison of the killing activity of WT-1 transduced T cells and your AIM-expanded T cells. Given your disclosure that the models were not identical and these results are not a head-to-head comparison, please tell us, and revise to discuss, if applicable, whether there were material differences between the models that could materially impact the comparison and conclusions presented.

Preliminary Data from the Phase I/II Clinical Trial, page 124

14. We note your statement on page 125 and on page 2 that the initial three patients in your Phase I/II clinical trial of NEXI-001 experienced "rapid and robust" lymphocyte reconstitution. Given your disclosure that normal return to baseline ALC takes 1-3 months, explain to us how you were able to conclude that the lymphocyte reconstitution was both rapid and robust. In this regard, the results for two of the three patients in the NEXI-001 trial appear to be within the bounds of normal lymphocyte recovery-to-baseline timelines.
15. Please revise to disclose where your ongoing clinical trials are conducted and indicate whether there are established endpoints for assessing safety and efficacy.

Johns Hopkins License Agreement, page 137

16. Please update your description of your exclusive license agreement as follows:
- Disclose separately the aggregate amount of all potential clinical and regulatory, diagnostic and non-clinical milestone payments;
 - Describe the circumstances that would lead to you being required to pay royalties on therapeutic products, diagnostic products and non-clinical products;
 - Quantify the potential increases in the minimum annual royalty payments in the future;
 - Revise your description of the non-royalty sublicense consideration to provide a range that does not exceed ten percent; and
 - Disclose when the royalty provisions expire.

Intellectual Property, page 138

17. Please revise your intellectual property subsection to indicate whether any of the material patents cover a specific technology or product candidate and identify the type of patent protection.

Description of Capital Stock, page 181

18. In this section, and elsewhere in your prospectus, you state that your outstanding shares of preferred stock, including shares of preferred stock issuable upon the automatic

Scott Carmer
NexImmune, Inc.
January 10, 2021
Page 5

conversion of all of your outstanding convertible promissory notes, will automatically convert into 196,970,172 shares of common stock upon the completion of the offering. However, in Dilution, Principal Stockholders, and Shares Eligible for Future Sale, you indicate that your outstanding shares of preferred stock, including automatic conversion of all outstanding convertible promissory notes, will convert into 201,162,009 shares of common stock. Please revise or explain to us how your disclosures are consistent.

Exhibits

19. We note that item 10.11 in your exhibit index refers to an exclusive license agreement by and between you and Johns Hopkins University dated June 21, 2011. Elsewhere in the prospectus, you statement that this agreement was amended and restated in January 2017. Please file the amended and restated agreement as an exhibit to your registration statement.

You may contact Gary Newberry at (202) 551-3761 or Kevin Kuhar at (202) 551-3662 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at (202) 551-4224 or Joe McCann at (202) 551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: John T. Rudy