



DIVISION OF
CORPORATION FINANCE

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

December 9, 2020

Geoff Green
Chief Executive Officer
LONGEVERON LLC
1951 NW 7th Avenue
Suite 520
Miami, FL 33136

Re: LONGEVERON LLC
Draft Registration Statement on Form S-1
Submitted November 12, 2020
CIK No. 0001721484

Dear Mr. Green:

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 filed November 12, 2020

Business Overview, page 1

1. We note your references on page 1 and elsewhere that "Lomecel-B has a high safety profile." Please revise your disclosure here and throughout your prospectus to remove your characterization of Lomecel-B as safe, as a determination of whether a product candidate is safe is solely within the authority of the U.S. Food and Drug Administration and comparable regulatory bodies. We will not object to statements that Lomecel-B was well-tolerated or information about the number of treatment related serious adverse events, but you should not state or imply that your product candidate is safe.

Clinical Development Pipeline, page 2

2. Please adjust the status bars in the pipeline graph, as appropriate, to illustrate your product candidate's current status for each indication. For example, with respect to your Aging Frailty indication, we note that your phase 2 trial is currently on-going, however, the pipeline graph appears to indicate that the phase 2 trial has been completed.
3. With respect to the Bahamas Registry Trial, the table appears to indicate that the product candidate has been approved but it is still described as a trial. Please revise your table to remove the indication that the product has been approved or provide additional clarification.

About Our Indications, page 3

4. We note your disclosure that there are no approved medications that can prevent, stop, or reverse the progression of Alzheimer's disease. However, according to the alzheimer's association website there appear to be two types of medications — cholinesterase inhibitors and memantine — that have been approved by the FDA to treat the cognitive symptoms of Alzheimer's disease. Please revise to clarify your statement or advise.

Financial Overview, page 4

5. Please balance your disclosure to also state that the Company has experienced significant losses since inception and expects to incur additional losses in the future.

We have been funded in part by government and non-profit grant awards..., page 15

6. Please describe the material terms and provisions of grant, contracts and regulations you must comply with for continued receipt of government and non-profit association funding. Additionally, we note your Exhibit Index appears to indicate your intention not to file the referenced contracts or funding agreements. Please provide us with an analysis supporting your conclusion that you are not required to file them pursuant to Item 601 of Regulation S-K.

Risks Related to Intellectual Property, page 20

7. We note that you may be subject to federal regulations, such as march-in rights. Please provide additional disclosure regarding the technology or technologies subject to march-in rights; the portion of your business that would be affected by the exercise of march-in rights; and whether and how you may be compensated in the event such rights are exercised.

Holders of our Class B common stock will control the direction of our business..., page 39

8. Please revise the discussion to identify the four holders you reference.

Industry and Other Data, page 48

9. Your statement that your internal company research as well as third party information regarding market and industry data has not been independently verified and that the accuracy and completeness of such information is not guaranteed implies a disclaimer of responsibility with respect to such information. Please either delete the statement or specifically state that you are liable for the information related to the market and industry data and your internal company research.

Use of Proceeds, page 48

10. We note your disclosure that you intend to allocate a portion of the proceeds from the offering to fund research, including clinical trials and product development for our existing pipeline. Please revise your disclosure identify each of the indications you intend to advance with the funds from the offering and how far in the development process for each indication you estimate that the allocated proceeds from the offering will enable you to reach.

Impact of COVID-19, page 54

11. We note your disclosure related to disruption in executing follow up visits and mitigation efforts. To the extent you had participants drop out of clinical trials, were not able to conduct follow up visits or need to increase the number of participants for any other reason related to pandemic related disruptions, please expand your disclosure to discuss these impacts and consider applicable risk factor disclosure.

Management's Discussion and Analysis of Financial Conditions and Results of Operations
Results of Operations

Research and Development Expenses, page 57

12. Given the importance of your research and development expenses to your operations, please consider including disaggregated disclosure of the nature of expenses incurred for each period.

Emerging Growth Company Status, page 63

13. Here and on page 7 you state you have elected to take advantage of the extended transition period for complying with new or revised accounting standards under Section 107(b) of the JOBS Act. However, your risk factor disclosure on page 41 states that you have irrevocably elected not to avail yourselves of this exemption from new or revised accounting standards. Please correct these apparent inconsistencies. If you elect to opt out of these provisions, please indicate as such on the cover page.

Our Strategy, page 64

14. Please remove statements that your grant funding awards "demonstrate the acceptance and support by the scientific community, giving high credibility to our programs," as many

research programs supported by the scientific community fail to achieve FDA approval.

Clinical Development Pipeline, page 66

15. With respect to Aging Frailty and Metabolic Syndrome, please also include in your discussion that according to the FDA, neither of such indications presently have definitions that are acceptable for characterizing the conditions for regulatory purposes and that the FDA and the Japanese PMDA have both indicated that the concept of “Frailty” or the Metabolic Syndrome as an indication will require additional clinical data and discussion before future pivotal trials and marketing authorization.

License Agreements and Strategic Collaborations, page 68

16. With respect to the License Agreement with the University of Miami, describe the nature of the use granted. For example, were you granted a worldwide exclusive license to develop and commercialize the intellectual property. Please also disclose the royalty term and the termination provisions under the agreement and quantify amounts paid to date, if any
17. With respect to the License Agreement with JMMD Holdings, describe the nature of the use granted. Please also disclose the royalty term and termination provisions. We also note your disclosure that there were no license fees due during the nine months ended September 30, 2020 and 2019 pertaining to this agreement. Please revise your disclosure to disclose the aggregate amounts paid under the agreement and potential milestone payments, if any.

U.S. Phase 2b Multicenter, Randomized, Double-Blinded, Placebo-Controlled Trial, page 72

18. We note your discussion of the Phase 2b clinical trial for your Aging Frailty Program. Please clarify whether there was a Phase Phase 2a trial and whether it has been completed.

Lomecel-B for Hypoplastic Left Heart Syndrome (HLHS), page 81

19. We note your disclosure that HLHS is an ultra-rare indication and would therefore qualify for an orphan drug designation and potentially for orphan drug exclusivity if FDA approved and that you may have the opportunity to pursue one of the FDA’s expedited review programs for this use. Please revise your disclosure to clarify, if true, that the FDA has not given any indication as to whether your product candidate will receive an orphan drug designation or exclusivity or be permitted to use expedited regulatory pathways.

Experts, page 131

20. Your expert language here only refers to the financial statements at December 31, 2019 and for the year then ended. Please revise to cover the same periods as the auditor’s report on page F-2.

Geoff Green
LONGEVERON LLC
December 9, 2020
Page 5

Financial Statements

Note 2. Summary of Significant Accounting Policies
Inventory, page F-7

21. Here you refer to a biological segment of your operations. Please clarify for us, and revise if necessary, whether you have reporting segments as defined under ASC 280. If so, please provide the required disclosures under ASC 280-10-50.

Intangible Assets, page F-8

22. Here you disclose that intangible assets include legal costs incurred related to patents and trademarks. You also disclose on page 55 that general and administrative expenses include legal fees relating to intellectual property. Please reconcile the two statements for us including clarifications for the nature of costs, and timing for asset recognition. Revise your disclosures if necessary. Please cite the relevant accounting references in your response.

Note 8. Commitments and Contingencies
Exclusive Licensing Agreements , page F-16

23. Please explain to us, and revise if necessary, how these licensing agreements contributed to your intangible assets disclosed on page F-8. Also, revise to disclose where you have included the annual fees paid under the UM agreement and the legal fees paid under the CD271+ agreement in the financial statements.

Exhibits

24. Please file the promissory note evidencing the Company's PPP loan as an exhibit to the registration statement, pursuant to Item 601(b)(10) of Regulation S-K. Alternatively, please explain to us why such disclosure is not required.

You may contact Li Xiao at 202-5514391 or Lynn Dicker at 202-551-3616 if you have questions regarding comments on the financial statements and related matters. Please contact Deanna Virginio at 202-551-4530 or Suzanne Hayes at 202-551-3675 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences