United States securities and exchange commission logo

June 28, 2024

Kristen Fortney, Ph.D.
Chief Executive Officer
BioAge Labs, Inc.
1445A South 50th Street
Richmond, California 94804

Re: BioAge Labs, Inc.
Draft Registration Statement on Form S-1
Submitted May 31, 2024
CIK No. 0001709941

Dear Kristen Fortney:

We have reviewed your draft registration statement and have the following comments.

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 a comment applies 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 this letter 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. We note that disclosures here, and elsewhere in the prospectus, include statements or implications that your product candidates are safe and/or effective. Please revise these statements, as safety and efficacy determinations are in the exclusive purview of the FDA or other regulators. For example only, the following statements improperly state or imply that your product candidates are safe or effective:

- On page 1, that azelaprag "prevented muscle atrophy, preserved muscle quality and improved metabolism."
- On page 2, that azelaprag "can recapitulate many of the benefits of exercise."
- On page 3, that azelaprag can "mimic some global effects of exercise at the protein level."
- On page 120, that azelaprag "significantly prevented [] bed-rest-induced muscle atrophy[.]"
- On page 121, that azelaprag "prevented the decrease in thigh circumference [], as well as in muscle diameter and thickness[.]"

2. We note your disclosure here, and on page 3, that in preclinical obesity models, azelaprag

demonstrated the ability to more than double the weight loss induced by a glucagon-like-
peptide-1 receptor (GLP-1R) agonist while also restoring healthy body composition and
improving muscle function. Please provide balancing disclosure with your statement on
page 20 that results of earlier studies and trials may not be predictive of future trial results.

Our approach: Targeting human aging biology to treat chronic metabolic diseases, page 1

3. Please ensure the text of the graphic is legible on page 2.

4. Please specify, if true, that the $150 billion estimate on page 2 refers to a global market, or
otherwise advise.

Our lead product candidate, azelaprag: an orally available, small molecule APJ agonist..., page 3

5. Please specify the number of volunteers in the Phase 1b clinical trial.

Our second product candidate, BGE-100, is a novel, orally available, brain-penetrant inhibitor of
NLRP3, a key target for neuroinflammation, page 6

6. Please provide the basis for the statement that inactivation of NLRP3 in mice has been
shown to significantly extend lifespan, with sustained physical and cognitive function. In
addition, please quantify the mice tested, or otherwise advise.

Risk Factors

Risks Related to Our Reliance on Third Parties

The manufacture of pharmaceutical products, including our product candidates..., page 43

7. We note your disclosure that you "currently contract with certain third-party
manufacturers, which are located in China" and that "since some of [y]our third-party
manufacturers are located in China, [you] are exposed to the possibility of product supply
disruption and increased costs in the event of changes in the policies of the United States
or Chinese governments[.]" We also note your disclosure regarding the BIOSECURE Act.
Please revise your disclosure to clarify whether any of the third-party manufacturers that
you currently contract with have been named as "companies of concern" in the current
U.S. House of Representatives version of the BIOSECURE Act.

Market and Industry Data, page 77

8. We note your statement that investors are cautioned not to give undue weight to market
estimates and projections. This statement appears to imply a disclaimer of responsibility
for this information in the registration statement. Please either revise this section to
remove such implication or specifically state that you are liable for all information in the

registration statement.

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

Critical Accounting Policies and Estimates

Stock-Based Compensation , page 99

9. Once you have an estimated offering price or range, please explain to us how you
determined the fair value of the common stock underlying your equity issuances and the
reasons for any differences between the recent valuations of your common stock leading
up to the initial public offering and the estimated offering price. This information will help
facilitate our review of your accounting for equity issuances including stock
compensation. Please discuss with the staff how to submit your response.

Our Strategy, page 112

10. Please remove the reference to "[p]otential first- and best-in-class APJ agonist" in the graphic as such descriptions imply an expectation of regulatory approval and are inappropriate given the length of time and uncertainty with respect to securing marketing approval.

Completed clinical trials, page 119

11. Please provide a more fulsome discussion of the seven Phase 1 trials, including when such trials occurred, and the specific dosing. In addition, please clearly disclose the primary and secondary endpoints, if any, and whether they were achieved.

12. We note your use of p-value on page 120, and elsewhere in the prospectus. At first use, please provide a brief explanation of the disclosed p-value and how it is used to measure statistical significance.

13. With respect to the Phase 1b clinical trial on page 120, please clarify whether the three referenced endpoints were primary or secondary.

Azelaprag for obesity: Genetic evidence supports the potential of azelaprag to improve metabolism..., page 125

14. With respect to the genetic studies of apelin in mice, please disclose whether you conducted such studies, the number of mice tested, and whether the observations were statistically significant.

Preclinical results in a diet-induced obesity model demonstrate the potential of azelaprag..., page 132

15. With respect to the BioAge Labs, Inc. trials, please disclose the number of mice tested, and whether the preclinical results were statistically significant.

Indication expansion opportunities, page 141

16. We note your disclosure regarding "robust evidence" indicating that "apelin has the potential to directly improve insulin sensitivity and glucose control" and "[r]obust preclinical evidence" indicating that "apelin signaling may have the potential to improve cardiac function in patients with heart failure." In both instances, please provide further details about the clinical studies and preclinical work that you reference in this section, including, but not limited to, who conducted the studies, what was observed, and whether the findings were statistically significant.

Approach for identifying novel targets based on unique insights into human aging biology, page 144

17. We note you have negotiated favorable agreements with biobanks, including SomaLogic and Metabolon, as well as your disclosure on page 2 that you have exclusive access to serial biobanked human samples. Please describe the material terms of the agreements with each biobank, and file each agreement as an exhibit

pursuant to Item
601(b)(10) of Regulation S-K or explain the basis for your
determination that filing is not
required.
Material Agreements
Exclusive License Agreement with Amgen Inc., page 146

18. Please clarify whether the Series C redeemable convertible preferred
stock held by Amgen
pursuant to the Amgen Agreement will be converted into common stock as
a result of the
offering and, if the Series C shares will be converted, please
disclose the number of shares
of common stock that Amgen will hold.
Intellectual Property
Azelaprag Program, page 149

19. With respect to the in-licensed 10 patent families from Amgen Inc.,
please provide the
patent expiration dates and expected expiration dates on an individual
or family basis for
the non-US pending patent applications. In addition, with respect to
the BGE-
100 Program s seven patent families and the Platform Technology and
Discovery
Program s four patent families, please disclose the patent
expiration dates and expected
expiration dates on an individual or family basis for the pending
patent applications.
20. We note your disclosure on page 150 that you have in-licensed one
patent family from the
Institut National De La Sante Et De La Recherche Medicale (INSERM)
relating to use of
the class of apelin receptor agonists for treating sarcopenia. Please
describe the material
terms of the license agreement, and file the agreement as an exhibit
pursuant to Item
601(b)(10) of Regulation S-K or explain the basis for your
determination that filing is not
required.

General

21. Please provide us with supplemental 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,
have presented or expect to present to potential investors in reliance
on Section 5(d) of the
Securities Act, whether or not you retained, or intend to retain,
copies of the
communications.

Please contact Eric Atallah at 202-551-3663 or Vanessa Robertson at
202-551-3649 if
you have questions regarding comments on the financial statements and related
matters. Please
contact Jimmy McNamara at 202-551-7349 or Joshua Gorsky at 202-551-7836 with
any other
questions.

Sincerely,

Division of
Corporation Finance

Office of Life
Sciences

cc: Julia Forbess