



DIVISION OF
CORPORATION FINANCE

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

April 17, 2020

Emmanuel Simons, Ph.D., M.B.A.
President and Chief Executive Officer
Akouos, Inc.
645 Summer Street
Boston, Massachusetts 02210

Re: Akouos, Inc.
Draft Registration Statement on Form S-1
Filed March 24, 2020
CIK No. 0001722271

Dear Dr. Simons:

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 clarify the meaning of any significant scientific or technical terms the first time they are used in the prospectus in order to ensure that lay readers will understand the disclosure. For example, and without limitation, please define each of the following at their first use in this section or where appropriate in the prospectus:
 - adeno-associated viral vector library
 - ancestral AAV
 - dual vector delivery
 - vector-mediated gene transfer
 - gene knockdown
 - vector-mediated therapeutic protein expression

2. We refer to the disclosure in the second paragraph regarding the number of people who live with disabling hearing loss. Please include disclosure regarding the market size for individuals suffering from the type of hearing loss that can be treated with your lead product candidate, AK-OTOF. Please provide similar disclosure on page 96 where you discuss the estimated annual costs associated with hearing loss.
3. We note your disclosure that the epidemiology and severity of the disorders you are initially targeting have the potential for more rapid clinical development and regulatory approval. Please clarify the reasons for the more rapid development and approval.
4. Please clarify the activities you have undertaken to sponsor and build The Sing Registry.

Our Pipeline, page 3

5. Please revise the label of the "Pivotal" column of the pipeline table to Phase 3. It is premature to suggest that the completion of the Phase 1/2 clinical trials will lead to a pivotal Phase 3 trial for the products listed in the table.
6. We note that your pipeline table includes five preclinical programs you are exploring. As your narrative disclosure only briefly discusses these programs and you have not allocated any proceeds for their development in your use of proceeds section, please explain to us why you believe these programs are sufficiently material to your business to be included in a pipeline table.

Risks Associated with Our Business, page 4

7. Please revise to highlight your first risk factor on page 10, which explains that you incurred significant losses during all fiscal periods since inception and expect to incur substantial losses for the foreseeable future.

Use of Proceeds, page 68

8. Please revise your disclosure in this section to indicate how far the proceeds from the offering will allow you to advance clinical development for AK-OTOF. Please also disclose the second product candidate for which you intend to initiate clinical development. In addition, please specify the amount of capacity of the internal manufacturing capabilities you intend to establish with proceeds from the offering.

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

Results of Operations, Comparison of the Years Ended December 31, 2018 and 2019, page 82

9. We see that you have multiple product candidates in various stages of development. If material, please revise to provide research and development expenses for the AK-antiVEGF and CLRN1 program, which are both also in the pre-clinical stage. In addition, provide a more robust discussion of the nature of research and development expenses generated each period for each significant product candidate. If based on a known event, trend, demand, commitment or uncertainty, future R&D expense or the mix

of R&D expense is reasonably likely to differ from current trends, please disclose the reasons for and the amount of the expected change. Reference Item 303(a)(3) of Regulation S-X.

Critical Accounting Policies and Significant Judgments and Estimates, Stock Based Compensation , page 87

10. Once you have an estimated offering price or range, please explain to us the reasons for any differences between the recent valuations of your common stock leading up to the IPO, the estimated offering price, and the consideration of preferred stock issuances. This information will help facilitate our review of your accounting for stock compensation.

Our Manufacturing Approach, page 119

11. Please clarify whether you will manufacture the surgical delivery devices to administer your product candidates or if that will be performed by an outside party.

Licensed Intellectual Property, page 123

12. The disclosure in this section states that the MEE License and Lonza Sublicense limit you to hearing diseases and disorders with total prevalence in the United States of less than 3,000 patients. Please tell us whether this limits your ability to generate revenues for these products given that the potential market sizes for the products under these licenses appear to be small.

General

13. 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.

You may contact Kristin Lochhead at (202) 551-3664 or Daniel Gordon at (202) 551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Chris Edwards at (202) 551-6761 or Celeste Murphy at (202) 551-3257 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Molly W. Fox, Esq.