



DIVISION OF
CORPORATION FINANCE

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

February 15, 2019

Andrew Cheng
President and Chief Executive Officer
Akeru Therapeutics, Inc.
170 Harbor Way, 3rd Floor
South San Francisco, CA 94080

Re: Akeru Therapeutics, Inc.
Draft Registration Statement on Form S-1
Submitted January 17, 2019
CIK No. 0001744659

Dear Mr. Cheng:

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

Prospectus summary

Overview, page 1

1. We note that you plan to initiate a Phase 2a clinical trial in the middle of 2019. Please disclose that you have not yet filed an investigational new drug application, or IND, for AKR-001 in NASH and that there is no assurance that submission of an IND will result in the FDA allowing a clinical trial to begin. Please disclose your expected timing for filing the IND with the FDA.
2. Please identify the sources for the market statistics that you provide in the prospectus summary and the Business section.

Our lead product candidate, AKR-001, page 1

3. We note your statement on page 2 and elsewhere that AKR-001 has the potential to be a best-in-class product. The term "best-in-class" suggests that the product candidate is effective and likely to be approved. Given the development stage of AKR-001 and length of the drug approval process, it is premature and inappropriate for you to imply that any of your product candidates will ultimately be approved or become best-in-class. Please delete these references throughout your registration statement.

Our strategy, page 2

4. Please revise the first bullet point to put into context your statement concerning your intention to "rapidly advance" AKR-001 through clinical development. In this regard, we note your disclosure on page 24 which indicates that clinical product development involves a lengthy and expensive process, with an uncertain outcome.

Implications of being an emerging growth company and a smaller reporting company, page 4

5. 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.
6. Please clarify in this section that you have elected the exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies.

Critical Accounting Policies and Significant Judgments and Estimates
Stock-based Compensation, page 86

7. 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 initial public offering and the estimated offering price. This information will help facilitate our review of your accounting for equity issuances including stock compensation.

Phase 1b clinical trial of AKR-001 in patients with TBD for 28 days, page 110

8. We note your reference to figure 5 in the last paragraph on page 112, but cannot locate the relevant graphic. Please revise for clarification.

Phase 1a clinical trial in type 2 diabetic patients, page 119

9. Please revise to provide more detail about the results observed in the Phase 1a clinical trial.

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Page 3

Choice of forum, page 174

10. We note that your forum selection provision identifies the Court of Chancery of the State of Delaware as the exclusive forum for certain litigation, including any “derivative action.” Please disclose whether this provision applies to actions arising under the federal securities laws. Also ensure that the exclusive forum provision in your proposed organizational documents states this clearly. In this regard, we note that Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder.

General

11. Please provide us proofs of all graphics, visual, or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.

You may contact Yolanda Trotter at (202) 551-3472 or Li Xiao at (202) 551-4391 if you have questions regarding comments on the financial statements and related matters. Please contact Chris Edwards at (202) 551-6761 or Coy Garrison at (202) 551-3466 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Healthcare & Insurance

cc: Laurie A. Burlingame