

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

January 16, 2014

Via E-mail
John P. Butler
President and Chief Executive Officer
Akebia Therapeutics, Inc.
245 First Street, Suite 1100
Cambridge, MA 02142

Re: Akebia Therapeutics, Inc.

Confidential Draft Registration Statement on Form S-1

Submitted December 20, 2013

CIK No. 0001517022

Dear Mr. Butler:

We have reviewed your confidential 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 confidential 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 confidential draft registration statement or filed registration statement, we may have additional comments.

General

- 1. Please submit all outstanding exhibits as soon as practicable. We may have further comments upon examination of these exhibits.
- 2. Please provide us proofs of all graphic, 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.
- 3. 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. Similarly, please supplementally provide us with any research reports about you that are published or distributed in reliance upon Section 2(a)(3) of the Securities Act of 1933 added by Section 105(a) of the Jumpstart Our Business Startups Act by any broker or dealer that is participating or will participate in your offering.

Risk Factors

Risks Related to Our Business and Industry

"If we fail to attract and keep senior management and key scientific personnel...," page 33

4. Please revise this risk factor to identify Mr. Daly as the executive officer currently also serving as an executive officer for Aerpio Therapeutics. Please additionally revise to compare the amount of time Mr. Daly is expected to devote to the affairs of Akebia to the amount of time he is expected to devote to Aerpio. Finally, please add a separate risk factor in this section describing any risks stemming from conflicts of interest that may arise from the association of Mr. Daly, certain of your directors, and any other of your employees with Aerpio.

Cautionary Note Regarding Forward-Looking Statements, page 45

5. Please note that it is not appropriate to state or imply that you do not have liability for the statements in your registration statement. Your statements in the last paragraph of this section that you have not independently verified market and industry data obtained from third-party sources could imply that you are not taking liability for the statistical and other industry and market data included in your registration statement. In order to eliminate any inference that you are not liable for all of the information in your registration statement, please delete these statements or include a statement specifically accepting liability for these statements.

Use of Proceeds, page 46

6. We note that you have not disclosed the amount of proceeds to be spent on any of the areas listed in the third paragraph of this section, such as research and development and clinical trial expenditures. However, if the company has specific purposes in mind for the use of proceeds, Item 504 of Regulation S-K requires disclosure of the approximate amount intended to be used for each such purpose. This is required even if, as you note in this section, management will have broad discretion in allocating the proceeds and the ultimate use of proceeds will depend on several contingencies subject to change. Please confirm that you will provide the respective amounts to be used for each purpose listed in this section in a future pre-effective amendment.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Critical Accounting Policies and Significant Judgments and Estimates
Stock-Based Compensation
Stock Awards, page 58

- 7. With regards to your retrospective valuations, please disclose what additional information was considered in the retrospective valuations that was not previously considered in the contemporaneous valuations and indicate what the contemporaneously determined valuations were for each valuation period presented.
- 8. Please note the following once your IPO price has been determined:
 - Please disclose the intrinsic value of outstanding vested and unvested options as of the most recent balance sheet date based on the estimated IPO price.
 - Please provide quantitative and qualitative disclosures explaining the difference between the estimated offering price and the fair value of each equity issuance.
 - Confirm that no additional equity issuances were made subsequent to the latest balance sheet or provide additional disclosure in that regard.
 - We may have additional comments on your accounting for stock compensation and related disclosure once you have disclosed an estimated offering price.

Business

Our Product Candidates, page 73

9. We note your inclusion in the pipeline chart on this page of Anemia of CKD (dialysis) and Idiopathic Age-related Anemia (IAA) as Phase 2 and Phase 1 indications, respectively. We also note your disclosure throughout your prospectus that you intend to initiate Phase 2 studies for the product candidate in these two indications. Please revise the pipeline chart and related disclosure to indicate, if true, that there have been no separate Phase 1 trials dedicated to CKD dialysis patients and patients with IAA. To the extent that you plan to use data from completed Phase 1 trials of AKB-6548 to advance the product candidate for these separate indications into Phase 2 trials, please ensure that the table and related disclosure accurately reflects this information.

AKB-6548 Clinical Development Overview, page 82

- 10. Please expand disclosure to indicate whether an investigational new drug (IND) application has been filed for AKB-6548 for each of the following indications:
 - Anemia of CKD (Non-Dialysis)
 - Anemia of CKD (Dialysis)
 - Idiopathic Age-related Anemia

If an IND application for each of the related indications has been filed, please disclose the date the application was filed and the identity of the filer. If an IND application for a listed indication has not been filed, please explain why, and clarify how you will be able to conduct clinical trials without an active IND on file with the FDA.

11. In the chart of your clinical trials on page 83, we note your disclosure of key findings for each trial. For each trial in which you report adverse events that were related to the study drug, please disclose the type of event and the frequency with which it occurred.

CI-0005: Positive Phase 2a Proof of Concept Trial, page 84

- 12. Please describe the primary clinical endpoints relating to this trial and the extent to which the endpoints were met.
- 13. Please expand disclosure to indicate the basis for your conclusions that each serious adverse event reported in this trial was not related to treatment with AKB-6548.

Ongoing and Planned Clinical Trials, page 87

14. We note that dosing in this trial will be adjusted in accordance with a protocol defined "Dose Adjustment Guidelines and Algorithm" and that the Phase 2b study will demonstrate the adaptive approach to dosing of AKB-6548. Please clarify these statements and explain how and at what point in your trials you plan determine optimal dosage, or range of dosage, for AKB-6548. For example, are the adjustment guidelines and algorithm subject to change based on pending Phase 2 results?

Projected Phase 3 Clinical Trials

15. We note your disclosure that endpoints, duration, and size of your Phase 3 trials will be based on those used in the Omontys (Peginesatide) approval studies. Please describe these endpoints and explain why the Omontys studies are an appropriate analogue for your Phase 3 trial design.

Third Party Filings, page 92

16. Please clarify what patents you refer to in the U.S. issued to FibroGen and why they might conflict with your intellectual property. Please also clarify how FibroGen could claim a method of using your product candidates in the U.S. for purposes of inhibiting HIF-PHs for treatment of anemia when your product candidates are protected by composition-of-matter patents. Please additionally include any revised disclosure in the risk factor on pages 24-25, as needed.

Executive Compensation, page 109

- 17. Please update this section to include the required disclosure for the most recently completed fiscal year. Please specifically include the 2013 as well as 2012 data in the summary compensation table and include all other updated compensation tables, narrative disclosure, and any other information required by Item 402 of Regulation S-K.
- 18. Please expand disclosure in this section to provide the material details of the employment agreement with Mr. Butler. Please disclose the initial base salary, the duration, and the renewal terms. Additionally, please fully describe the terms of the agreement relating to the payment of incentive bonuses. Further, please ensure that in your next amendment, Mr. Butler is identified as a named executive officer in accordance with Item 402(a)(3)(i) of Regulation S-K and that you provide all other relevant disclosure for Mr. Butler required by Item 402.

<u>Certain Relationships and Related Party Transactions</u> Services Agreement, page 120

19. Please expand disclosure to describe all material terms of this agreement. Please also specifically disclose the services provided as consulting services and the specific facilities and equipment subject to the agreement in this section. Please additionally disclose the amounts paid in each of the last three fiscal years and the interim periods under the agreement. Finally, please file this agreement as an exhibit to your registration statement.

Description of Capital Stock, page 125

20. Please disclose the voting rights applicable to holders of your common stock.

Shares Eligible for Future Sale, page 130

21. Please file the form of lock-up agreement as an exhibit to your registration statement.

Balance Sheets, page F-3

22. As required by ASC 505-10-50-4, please provide disclosure regarding the liquidation preference of the stock in the aggregate, either parenthetically or in short, or tell us why the disclosure is not required.

Note 12. Stock Based Compensation Restricted Stock, page F-34

- 23. Please provide us your accounting basis to support your accounting for the restricted stock issued to employees in exchange for promissory notes. Tell us and disclose where you recorded the promissory notes in the financial statements. Refer to ASC 505-10-45-2. In your response, please explain the difference in accounting for the promissory notes as nonrecourse in their entirety as opposed to 50% recourse to employees.
- 24. We note your disclosure that the promissory notes along with the issuance of the restricted stock are in substance similar to the grant of an option with the exercise price being the principal due on the note. In that regard, please explain and disclose in more detail how the structure of the transaction works and how it is similar to an option since the restricted stock had been issued.

Note 15. Net Loss per Share, page F-37

25. Please provide reconciliations of the numerators and denominators with respect to your calculations of pro forma earnings per share data.

Signatures

26. Please note that when filed the registration statement should also be signed by the company's controller or principal accounting officer. Any person who occupies more than one of the specified positions required to sign the registration statement should indicate each capacity in which the registration statement is signed. See Instructions to Signatures to Form S-1.

If you intend to respond to these comments with an amended draft registration statement, please submit it and any associated correspondence in accordance with the guidance we provide in the Division's October 11, 2012 announcement on the SEC website at http://www.sec.gov/divisions/corpfin/cfannouncements/drsfilingprocedures101512.htm.

Please keep in mind that we may publicly post filing review correspondence in accordance with our December 1, 2011 policy (http://www.sec.gov/divisions/corpfin/cfannouncements/edgarcorrespondence.htm). If you intend to use Rule 83 (17 CFR 200.83) to request confidential treatment of information in the correspondence you submit on EDGAR, please properly mark that information in each of your confidential submissions to us so we do not repeat or refer to that information in our comment letters to you.

You may contact Sasha Parikh at (202) 551-3627 or Andrew Mew at (202) 551-3377 if you have questions regarding comments on the financial statements and related matters. Please

contact Austin Stephenson at (202) 551-3192, John Krug at (202) 551-3862, or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Daniel Greenspan for

Jeffrey P. Riedler Assistant Director

cc: Via E-mail

Monica Singh, Esq. Ropes & Gray LLP