

Akebia Therapeutics, Inc.

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Submitted Pursuant to a Request for Confidential Treatment Pursuant to 17 C.F.R. 200.83

January 20, 2017

#### VIA EDGAR

Securities and Exchange Commission Division of Corporation Finance 100 F Street, N.E. Washington, D.C. 20549

Attention: Mr. Jim B. Rosenberg

Mr. Rolf Sundwall Ms. Keira Nakada

Re: SEC Comment Letter dated December 22, 2016

Akebia Therapeutics, Inc.

Form 10-K for the Fiscal Year Ended December 31, 2015 Filed March 14, 2016

Form 10-Q for the Quarterly Period Ended September 30, 2016 Filed November 9, 2016

File No. 001-36352

Set forth below is the response of Akebia Therapeutics, Inc. (the "Company") to the letter dated December 22, 2016 from Jim B. Rosenberg of the Staff (the "Staff") of the Securities and Exchange Commission (the "Commission") to Jason A. Amello, the Company's Senior Vice President, Chief Financial Officer and Treasurer, with respect to the Company's Form 10-K for the fiscal year ended December 31, 2015 (filed March 14, 2016), and Form 10-Q for the quarterly period ended September 30, 2016 (filed November 9, 2016), File No. 001-36352.

For reference purposes, the Staff's comments as reflected in the Staff's letter dated December 22, 2016 are reproduced in italics in numerical sequence in this letter, and the corresponding responses of the Company are shown below each comment.

Please contact me at (617) 871-2087 if you have any questions regarding this response to the Staff comment letter.

Sincerely,

/s/ Jason A. Amello

Jason A. Amello

Senior Vice President, Chief Financial Officer and Treasurer

Confidential treatment has been requested for portions of this letter. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [\*\*\*\*\*]. A complete version of this letter has been separately filed with the Securities and Exchange Commission.

**Confidential Treatment Requested By** Akebia Therapeutics, Inc.

## Form 10-Q for the Quarterly Period Ended September 30, 2016 **Notes to Condensed Consolidated Financial Statements** 9. Significant Agreements, page 20

Comment No. 1: Please tell us how you applied ASC 605-25, Revenue Recognition in Multiple-Element Arrangements, as it relates to your Mitsubishi Tanabe Pharma Collaboration Agreement. In this regard, provide us the information required by ASC 605-25-50-2 in your response.

## Response to Comment No. 1

As of the time we executed the collaboration agreement with Mitsubishi Tanabe Pharma Corporation (MTPC) in December 2015 (Collaboration Agreement) and through the date of this letter, we are unable to determine each of the deliverables we will be obligated to deliver to MTPC and the amount of total consideration we would receive under the agreement. All of the deliverables will not be known until such time as Akebia (Company) and MTPC in consultation with the Pharmaceuticals and Medical Devices Agency (PMDA), the Japanese regulatory authority, determines whether Japanese subjects are to be enrolled in our ongoing global Phase 3 study of vadadustat (Global Scenario) or, alternatively, if PMDA will require MTPC to conduct a separate study in Japan with only Japanese subjects (Local Scenario). The final determination of whether Japanese patients can be included in the global Phase 3 study will be made by the PMDA following the results of our Phase 2 studies being conducted in Japan, which is expected in the second half of 2017, unless the Company and MTPC otherwise decide to pursue the Local Scenario prior to such determination.

Under a Global Scenario, our deliverable will be a "Services Deliverable" as we will be required to include Japanese subjects in our ongoing global Phase 3 study. In this scenario, we are entitled to receive up to \$80.0 million from MTPC for reimbursement of costs of the Phase 3 study, of which \$20.0 million was received in January 2016. Under a Local Scenario, our deliverable will be a "Supply Deliverable" as we will not be including Japanese subjects in our global Phase 3 study but will be required to provide clinical supply of vadadustat to MTPC in order for MTPC to conduct a local study. Under this Local Scenario we will not receive any additional consideration from MTPC for reimbursement of costs of our global Phase 3 study.

The Company evaluated the Collaboration Agreement in accordance with the provisions of ASC 605-25. The Company's arrangement with Mitsubishi Tanabe contains different deliverables and units of accounting under each of the Global Scenario and Local Scenario, both are which are summarized on the following pages:

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\*\*\*\*\*Confidential material redacted and separately filed with the Securities and Exchange Commission

### GLOBAL SCENARIO

Deliverables Units of Accounting

#### License

The license conveyed to MTPC in connection with the Collaboration Agreement represents a deliverable because it embodies the right to use certain assets (i.e., intellectual property) controlled by the Company that were bargained-for elements of the arrangement.

# **Development Services**

Akebia is responsible for the development and regulatory approval in Japan. In return for that obligation, MTPC provides additional consideration of up to \$80.0 million through the reimbursement of the development costs. The Company includes all costs incurred related to the Phase 3 program, as well as any other clinical studies required ("Development Services"). As such, the performance of the Development Services is considered a deliverable.

#### **Knowledge Transfer**

The Knowledge Transfer constitutes a deliverable because it was a bargained-for element of the arrangement that requires a distinct action by the Company. Such obligations represent deliverables as they are considered necessary and important to MTPC and MTPC cannot perform its planned development activities without the Company providing this data.

#### License and Development Services

The License and Development Services unit of accounting is comprised of a combination of deliverables, including the License to the Company's technology, the Development Services, and Knowledge Transfer. The License does not have standalone value separate from the Development Services, as the License conveyed does not provide MTPC with the ability to develop or commercialize the underlying product(s) without the corresponding Development Services and consequently, MTPC cannot fully exploit the value of the Licenses conveyed without the receipt of the underlying Development Services. Similarly, the License does not have standalone value from the Knowledge Transfer deliverable, as MTPC cannot fully utilize the license for its intended purpose without the corresponding information regarding know-how, development data and regulatory materials possessed by the Company. MTPC would not be able to fully exploit the License by conducting its own clinical trials without the ability to use and reference information and data provide through the Knowledge Transfer.

## Rights to Future Know-How

The Rights to Future Know-How constitute a deliverable under the arrangement as the provisions allow for MTPC to obtain access to intellectual property that does not yet exist.

#### Rights to Future Know-How

The License has standalone value from the Rights to Future Know-How because MTPC can obtain the value of the License using the clinical supply materials and Knowledge Transfer without the receipt of any Rights to Future Know-How. There are no known or expected new third-party licenses, additional patents or license improvements that are required for MTPC to use the License, clinical supply materials or Knowledge Transfer for their intended purpose. The Company believes that the License could be sold separately or resold on a standalone basis without the potential future intellectual property that would be conveyed through the Rights to Future Know-How at a price that would substantially recover the original purchase price. As the Collaboration Agreement does not include a general right of return, both the conditions in ASC 605-25-25-5 are satisfied and the Company concludes that the License unit of accounting qualifies for separation from the Rights to Future Know-How.

## Joint Steering Committee

The obligation under the Joint Steering Committee (JSC) in a Global Scenario is participatory as MTPC would acquire information obtained through the Phase 3 program via the JSC which MTPC may need for development in the non-Japan countries in the Territory. Since the Company will be conducting the Phase 3 program, their participation in the JSC is material to MTPC.

## Joint Steering Committee

The JSC has standalone value because although the members of the JSC are senior level executives that have specialized industry knowledge and extensive experience, the Company believes that other knowledgeable professionals could sufficiently perform the duties of the Joint Steering Committee.

Under a Global Scenario, the entire arrangement fee will be allocated to the License and Development Services unit of accounting. Since the License is delivered at the inception of the arrangement, the revenue recognition for the combined unit of account will follow the pattern of recognition for the Development Services. The Company has determined that the proportional performance method is the most appropriate revenue recognition model for the Development Services. Notwithstanding, the Company acknowledges that it may not have adequate information to discern the pattern of performance of the Development Services at the time revenue recognition commences. This will be dependent on the availability of information related to the conduct of the global Phase 3 trial. In the absence of a discernable pattern, the Company may conclude that straight line revenue recognition is the best measure of performance or otherwise not materially different than a proportional performance method. Therefore, if under a Global Scenario, the Company will make a determination which revenue recognition pattern is most appropriate. In addition, since the payments for reimbursement are contingent upon the performance of services, the Company will ensure that the cumulative revenue recognized does not exceed the non-contingent payments under the arrangement. At the time revenue recognition commences under a Global Scenario, the Company expects that a material portion of the Development Services will have been provided. As such, the Company will be required to make a policy election whether to recognize the cumulative deferred revenue prospectively as the remaining services are provided or record a cumulative catch up adjustment.

### LOCAL SCENARIO

Deliverables Units of Accounting

#### License

The License conveyed to MTPC in connection with the Collaboration Agreement represents a deliverable because it embodies the right to use certain assets (i.e., intellectual property) controlled by the Company that were bargained-for elements of the arrangement.

#### **Clinical Supply Obligations**

Akebia is responsible for manufacturing and supplying all reasonable requirements of product for clinical and commercial use in the Territory. The Company's obligation to supply clinical trial materials constitutes a deliverable under the Local Scenario because it represents a contractual requirement to provide goods.

Conversely, although the Collaboration Agreement contemplates that the Company will provide commercial product or, at a minimum, the Active Pharmaceutical Ingredient ("API") for the commercial product, this obligation is not considered to be a deliverable, as the commercial supply or API would be contingent upon approval of vadadustat. Due to the nature of the pharmaceutical industry, there is considerable uncertainty about the outcome of the contingency. The fee the customer will have to pay for commercial product is reasonable and does not represent a significant incremental discount. Accordingly, the Company has not treated the obligation to provide commercial manufacturing and supply as a separate element of the arrangement and no portion of the arrangement consideration will be allocated to this item.

## Knowledge Transfer

The Knowledge Transfer constitutes a deliverable because it was a bargained-for element of the arrangement that requires a distinct action by the Company. Such obligations represent deliverables as they are considered necessary and important to MTPC and MTPC cannot perform its obligations under the Collaboration Agreement without the Company providing this data.

#### License and Clinical Supply

The License and Clinical Supply unit of accounting is comprised of a combination of deliverables, including the License to the Company's technology, the Clinical Supply Obligations, and Knowledge Transfer. The License does not have standalone value separate from the Clinical Supply Obligations, as the license conveyed does not provide MTPC with the ability to manufacture either clinical trial materials or commercial product. The value in the rights provided will be realized when the underlying product(s) covered by the intellectual property progress through the development cycle, receive regulatory approval and are commercialized. However, the underlying product(s) cannot be developed or commercialized without the corresponding clinical trial materials and consequently, MTPC cannot fully exploit the value of the licenses conveyed without the receipt of the underlying clinical materials.

Similarly, the License does not have standalone value from the Knowledge Transfer deliverable, as MTPC cannot fully utilize the license for its intended purpose without the corresponding information regarding know-how, development data and regulatory materials possessed by the Company. MTPC would not be able to fully exploit the license by conducting its own clinical trials without the ability to use and reference information and data provide through the Knowledge Transfer.

# Rights to Future Know-How

The Rights to Future Know-How constitute a deliverable under the arrangement as the provisions allow for MTPC to obtain access to intellectual property that does not yet exist.

## Rights to Future Know-How

The License has standalone value from the Rights to Future Know-How because MTPC can obtain the value of the License using the clinical supply materials and Knowledge Transfer without the receipt of any Rights to Future Know-How. There are no known or expected new third-party licenses, additional patents or license improvements that are required for MTPC to use the License, Clinical Supply Materials or Knowledge Transfer for their intended purpose. The Company believes that the License could be sold separately or resold on a standalone basis without the potential future intellectual property that would be conveyed through the Rights to Future Know-How at a price that would substantially recover the original purchase price. As the Collaboration Agreement does not include a general right of return, both the conditions in ASC 605-25-25-5 are satisfied and the Company concludes that the License unit of accounting qualifies for separation from the Rights to Future Know-How.

Under a Local Scenario, the entire arrangement fee will be allocated to the License and Clinical Supply unit of accounting. The obligations included within the License and Clinical Supply unit of accounting are comprised of license-related and supply-related deliverables. The license is delivered at inception of the arrangement upon execution of the agreement. Similarly, the initial delivery of information and materials related to the Company's obligations under the Knowledge Transfer deliverable is considered complete shortly after execution of the agreement which is consistent with the 45-day time period ascribed to the transfer. Therefore, the only undelivered item relates to the clinical supply obligation. The clinical supply obligation will be fulfilled throughout the term of the arrangement as MTPC works to advance the underlying product(s) through the development cycle in a Local Scenario. The Company has determined that the revenue recognition model applicable to the License and Clinical Supply unit of accounting should be followed in recognizing revenue for the combined unit of accounting. Accordingly, the consideration should be recognized as revenue as the clinical supply is delivered (assuming all materials have met any required specifications and the related title and risk of loss have passed) commencing on the date of the first delivery of the associated product. The Company believes that once it is determined if the parties will be operating under a Local Scenario, the Company will have the ability to either estimate the amount of materials to

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be provided or the period over which the materials will be delivered. The Company anticipates having a clinical supply agreement and a development plan in place which may provide adequate information to enable the Company to reliably estimate the total amount of clinical trial materials expected to be provided and the pattern over which the underlying products will be delivered, which would allow the Company to recognize the revenue using a proportional performance method. However, at the time the Local Scenario development plan and supply agreement are approved, if there is uncertainty regarding the amount of clinical supply and the pattern of performance cannot be discerned, the Company may recognize revenue on a straight line basis.

The Company has determined that neither vendor-specific objective evidence (VSOE) of selling price nor third-party evidence (TPE) of selling price is available for any of the units of accounting identified at inception of the arrangement with MTPC. Given the nature of the rights to Future Know-How unit of accounting, the Company has determined that neither VSOE nor TPE of selling price exists. Further, the Company has determined that its best estimate of selling price for the rights to Future Know-How unit of accounting is de minimis and therefore the determination of estimates of selling price for each individual unit of accounting is unnecessary as the allocable arrangement consideration will be attributed to the License unit of accounting in its entirety. Allocable arrangement consideration at inception is the fixed or determinable amount of the up-front payment of \$20.0 million.

Given the uncertainty around both the deliverables and the total consideration to be received, we concluded that we lack sufficient persuasive evidence of an arrangement until these uncertainties are resolved (that is, there is uncertainty regarding our rights and obligations under the arrangement). As a result, we have not yet commenced revenue recognition and deferred the \$40.0 million of upfront and development payments we received in January 2016. The disclosures in our 2015 Form 10-K and each of our 2016 Form 10-Qs, based on disclosures of other industry participants with similar circumstances, were focused on the inclusion of a revenue recognition policy in our significant accounting policies rather than the application of ASC 605 to the MTPC arrangement since revenue recognition had not yet commenced. We expected to apply the recognition and disclosure provisions of ASC 605 in the second half of 2017 when we believe revenue recognition would commence. In response to the Staff's comment we will revise the disclosure to be included in our 2016 Form 10-K, to be filed with the SEC in March of 2017. A draft of the disclosure we plan to include in our 2016 Form 10-K is provided below. This disclosure will also include information related to the milestone payments that we believe is most meaningful to readers of our financial statements. Once it has been determined under which scenario vadadustat will be developed for the Japan market, we will then have persuasive evidence of an arrangement and we will include the required disclosures of ASC 605 pertaining to the deliverables, units of accounting and allocation of consideration, which we expect will be in the second half of 2017.

## Form 10-Q for the Quarterly Period Ended September 30, 2016 Notes to Condensed Consolidated Financial Statements 9. Significant Agreements, page 20

Comment No. 2: Regarding the \$350 million of total milestone payments you are eligible to receive under the Mitsubishi Tanabe Pharma Collaboration Agreement, please address the following:

- Provide an analysis of each milestone under ASC 605-28-20; and
- Provide us the information required by ASC 605-28-50-2.b, c, and d for each milestone that meets the definition of a milestone under ASC 605-28-20.

#### Response to Comment No. 2

The Agreement with MTPC provides for the following payments, totaling up to \$350.0 million under various outcomes:

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\*\*\*\*\*Confidential material redacted and separately filed with the Securities and Exchange Commission

## AKEBIA THERAPEUTICS, INC. MTPC SUMMARY OF PAYMENTS (in million USD)

		Global Scenario [****]				Local Scenario	
	[****]	Outcome 1	Outcome 2	Outcome 3	Outcome 4	Outcome 1	Outcome 2
LICENSE FEE	[****]	20	20	20	20	20	20
R&D FUNDING	[****]	80	80	80	80		
NON-REFUNDABLE AND NON-CREDITABLE	·			· · · · · · · · · · · · · · · · · · ·			· · ·
MILESTONES:							
Development Milestones	[****]	10	[****]	[****]	[****]	[****]	[****]
Regulatory Milestones	[****]	65	[****]	[****]	[****]	[****]	[****]
Sales Milestones	[****]	175	[****]	[****]	[****]	[****]	[****]
Total Milestones	[****]	250	[****]	[****]	[****]	[****]	[****]
TOTAL PAYMENTS	[****]	350	[****]	[****]	[****]	[****]	[****]

Each of the above milestones are payable only once.

We will include in our revised disclosure, information related to the milestone payments that we believe is most meaningful to the readers of our financial statements.

# Proposed Disclosure to be included in the Financial Statements in our 2016 Form 10-K

#### Mitsubishi Tanabe Pharma Collaboration Agreement

Summary of Agreement

On December 11, 2015, the Company and MTPC entered into a collaboration agreement (Collaboration Agreement) providing MTPC with exclusive development and commercialization rights to vadadustat, the Company's product candidate for the treatment of anemia related to chronic kidney disease, in Japan and certain other Asian countries (collectively, the Territory).

Pursuant to the Collaboration Agreement, MTPC will have an exclusive license to develop and commercialize vadadustat in the Territory. In addition, the Company will supply vadadustat for both clinical and commercial use in the Territory. The countries included in the Territory are Japan, Taiwan, South Korea, Singapore, Malaysia, India, Indonesia, East Timor, Mongolia, the Philippines, Vietnam, Laos, Cambodia, Thailand, Brunei, Myanmar, Nepal, Sri Lanka, Bangladesh, Bhutan, Maldives, Palau and Tonga and their territories and possessions.

In consideration for the exclusive license and other rights contained in the Collaboration Agreement, MTPC will make payments totaling up to \$350.0 million to fund the vadadustat Phase 3 program (Phase 3 Program), including up to \$100.0 million in upfront and development payments, of which \$40.0 million was received in January 2016. To the extent Japanese patients are included in the Phase 3 Program, MTPC will fund up to an additional \$60.0 million of development costs (Global Scenario). If Japanese patients are not included in the Phase 3 Program (Local Scenario), MTPC will be responsible for the costs of the local Phase 3 study in Japan and make no additional funding payments for the Phase 3 Program. In addition, \$20.0 million of the \$40.0 million received in 2016 would be used to fund MTPC's local development of vadadustat in Japan or be refunded to MTPC, at MTPC's discretion.

The final determination of whether Japanese patients can be included in the Phase 3 Program will be made by the Company and MTPC in consultation with the Pharmaceuticals and Medical Devices Agency (PMDA) following the results of our Phase 2 studies being conducted in Japan, which is expected in the second half of 2017, unless the Company and MTPC otherwise collectively decide, as provided in the Collaboration Agreement, to pursue the Local Scenario prior to such determination by the PMDA.

The Company is also eligible to receive up to approximately \$250.0 million in additional payments, based upon achievement of certain development, regulatory and sales milestones as well as tiered double-digit royalty payments on sales of vadadustat in the Territory.

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\*\*\*\*\*\*Confidential material redacted and separately filed with the Securities and Exchange Commission

# Confidential Treatment Requested By Akebia Therapeutics, Inc.

The Company has evaluated all of the development, regulatory and sales milestones that may be received in connection with the Collaboration Agreement. In evaluating if a milestone is substantive, the Company assesses whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. All development and regulatory milestones are considered substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. The total aggregate amount of development milestones is \$10.0 million and the total aggregate amount of approval milestones is up to \$65.0 million. All sales milestones, up to \$175.0 million, will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

The Company and MTPC have established a joint steering committee to oversee development and commercialization of vadadustat in the Territory, including approval of any development or commercialization plans. Unless earlier terminated, the Collaboration Agreement will continue in effect on a country-by-country basis until the later of: expiration of the last-to-expire patent covering vadadustat in such country in the Territory; expiration of marketing or regulatory exclusivity in such country in the Territory; or ten (10) years after the first commercial sale of vadadustat in such country in the Territory. MTPC may terminate the Collaboration Agreement upon twelve (12) months' notice at any time after the second anniversary of the effective date of the Collaboration Agreement. Either party may terminate the Collaboration Agreement upon the material breach of the other party that is not cured within a specified time period or upon the insolvency of the other party.

As of December 31, 2016, the Company cannot determine all of its deliverables or the total amount of consideration to be received for which revenue will be recognized until it knows whether vadadustat will be developed for the Japan market under a Global Scenario or under a Local Scenario. Given the uncertainty around both the deliverables and the total consideration to be received, we concluded that we lack sufficient persuasive evidence of an arrangement until these uncertainties are resolved (that is, there is uncertainty regarding our rights and obligations under the arrangement). Under a Global Scenario, our deliverable will be a Services Deliverable as we will be required to include Japanese subjects in our ongoing global Phase 3 study. Under a Local Scenario, our deliverable will be a Supply Deliverable as we will not include Japanese subjects in our ongoing Phase 3 program, but will instead provide clinical supply of vadadustat to MTPC in order for MTPC to conduct a local study. The final determination will be made by the Company and MTPC in consultation with the PMDA following the results of our Phase 2 studies being conducted in Japan, unless the Company and MTPC otherwise decide to pursue the Local Scenario prior to such consultation with the PMDA. Revenue recognition for the Collaboration Agreement will commence when all criteria as required under ASC 605 have been satisfied, which the Company expects will be in the second half of 2017. Therefore, the \$40.0 million payment received in January 2016 is recorded as deferred revenue in the accompanying consolidated balance sheet.

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\*\*\*\*\*Confidential material redacted and separately filed with the Securities and Exchange Commission