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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**Amendment No. 1  
to  
FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

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**AKEBIA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

2834  
(Primary Standard Industrial  
Classification Code Number)  
245 First Street, Suite 1100  
Cambridge, MA 02142  
(617) 871-2098

20-8756903  
(I.R.S. Employer  
Identification Number)

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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**John P. Butler**  
**President and Chief Executive Officer**  
Akebia Therapeutics, Inc.  
245 First Street, Suite 1100  
Cambridge, MA 02142  
(617) 871-2098

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to public:** As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Non-accelerated filer

(Do not check if a smaller reporting company)

Accelerated filer

Smaller reporting company

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**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED March 3, 2014**

PRELIMINARY PROSPECTUS

## Shares



This is the initial public offering of shares of common stock of Akebia Therapeutics, Inc.

We are offering \_\_\_\_\_ shares of our common stock. Prior to this offering, there has been no public market for our common stock. We have applied to have our common stock listed on the NASDAQ Global Market under the trading symbol "AKBA."

We are an emerging growth company under the federal securities laws and are subject to reduced public company reporting requirements.

**Investing in our common stock involves a high degree of risk. See "[Risk Factors](#)" beginning on page 11.**

	<u>Per share</u>	<u>Total</u>
Initial public offering price	\$ _____	\$ _____
Underwriting discounts and commissions(1)	\$ _____	\$ _____
Proceeds, before expenses, to Akebia	\$ _____	\$ _____

(1) See "Underwriting" for additional disclosure regarding underwriting discounts, commissions and expenses.

To the extent that the underwriters sell more than \_\_\_\_\_ shares of common stock, the underwriters have an option to purchase up to an additional \_\_\_\_\_ shares from us at the initial public offering price, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The underwriters expect to deliver the shares against payment in New York, New York on \_\_\_\_\_, 2014.

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

**Morgan Stanley**

**UBS Investment Bank**

**Credit Suisse**

**Nomura**

, 2014

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We are responsible for the information contained in this prospectus and in any free-writing prospectus we prepare or authorize. We have not, and the underwriters have not, authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the cover page of this prospectus.

## Summary

*This summary highlights information contained in other parts of this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes and the information set forth under the sections titled “Risk Factors,” “Cautionary Note Regarding Forward-Looking Statements” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Unless the context requires otherwise, references in this prospectus to “Akebia,” “we,” “us,” “our,” the “Company” and similar designations refer to Akebia Therapeutics, Inc.*

### Overview

We are a biopharmaceutical company focused on the development of novel proprietary therapeutics based on hypoxia inducible factor, or HIF, biology and the commercialization of these products for patients with kidney disease. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body and a potentially novel mechanism of treating anemia. Our lead product candidate, AKB-6548, is being developed as a once-daily oral therapy that has successfully completed a Phase 2a proof of concept study demonstrating that AKB-6548 safely and predictably raised hemoglobin levels in patients with anemia secondary to chronic kidney disease, or CKD, not requiring dialysis.

We are conducting a Phase 2b trial for AKB-6548 in patients with anemia secondary to CKD who are not dependent on dialysis and expect data to be available in the fourth quarter of 2014. We have also initiated a development program for patients dependent on dialysis. If the results of our Phase 2b trial are positive, we would expect to initiate Phase 3 trials for anemia secondary to CKD in 2015, and would anticipate submitting a New Drug Application, or NDA, for AKB-6548 in the United States by 2018 if the Phase 3 data are favorable.

We own worldwide rights to our HIF-based product candidates, including AKB-6548. If approved by regulatory authorities, we plan to commercialize AKB-6548 in the United States ourselves and intend to seek one or more collaborators to commercialize the product candidate in additional markets.

Anemia is a serious medical condition in which blood is deficient in RBCs and hemoglobin, both of which are critical in delivering oxygen to tissue. Anemia generally exists when hemoglobin, a protein in RBCs that carries oxygen, is less than 13 g/dL in men or 12 g/dL in women. Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases and death. Anemia is common in patients with CKD, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly.

More than 30 million people in the United States have CKD, with estimates that over 1.8 million of these patients suffer from anemia. Anemia from these indications is currently treated by injectable recombinant protein erythropoiesis stimulating agents, or rESAs—including Epogen, Aranesp and Procrit—with iron supplementation or an RBC transfusion. Based on the reported revenues of companies that market and sell rESAs, we estimate that global sales of injectable rESAs were \$6.3 billion in 2012, the vast majority of which were for renal indications.

rESAs are designed to stimulate production of RBCs by binding directly to and saturating erythropoietin, or EPO, receptors. While injectable rESAs and transfusions may be effective in raising hemoglobin levels, they carry significant potential side effects and also need to be delivered subcutaneously or intravenously. In particular, injectable rESAs may lead to thrombosis, stroke, myocardial infarction and death, and these risks are described in black box warnings on the prescribing information of all products marketed in this class. These safety concerns, which became evident starting in 2006, have led to a significant reduction in the use of

injectable rESAs. Today anemia is either not treated or inadequately treated in the majority of CKD patients, and we believe that a safe, effective, oral therapeutic option will take significant market share and meaningfully grow the market in patients not requiring dialysis.

AKB-6548 works by a differentiated mechanism of action that we believe has the potential to be safer than that of injectable rESAs. This novel mechanism of action is referred to as HIF prolyl-hydroxylase, or HIF-PH, inhibition. Instead of binding directly to the EPO receptors on cells in the bone marrow, AKB-6548 leads to activation of critical pathways for hemoglobin and RBC production. This approach mimics the physiological adjustment made by the body when exposed to reduced oxygen levels at higher altitudes.

To date, AKB-6548 has been studied in eight clinical trials across four separate patient populations: healthy volunteers and patients with CKD stages 3, 4 and 5 (non-dialysis). Our largest study was a Phase 2a trial in 91 patients with anemia secondary to CKD, which showed significantly increased hemoglobin levels among subjects taking AKB-6548 compared to baseline in a dose-dependent manner across all treatment arms ( $p < 0.0001$ ). No drug-related serious adverse events were reported, and dosing was well-tolerated. In addition, AKB-6548 was also shown to stabilize the iron supply to the bone marrow while improving hemoglobin production.

Our ongoing Phase 2b trial explores a dosing approach for AKB-6548 to enable subjects with anemia secondary to CKD to appropriately and safely raise hemoglobin levels. As of February 28, 2014, we had enrolled over 80% of our targeted 200 patients in this study at investigational sites in the United States, with data expected in the fourth quarter of 2014. With positive data, we plan to progress to Phase 3 global registration studies for AKB-6548 in patients with anemia secondary to CKD. We anticipate the design of the Phase 3 studies will mirror the Phase 2b study, except that they will be longer and larger in size, positioning us to file for approval in the United States by 2018.

Given the burdens of the current standard of care and costs associated with administering an injectable rESA, we believe AKB-6548 is a promising alternative for the overall cost-effective treatment of anemia. We intend to commercialize AKB-6548 ourselves in the United States for the treatment of anemia in patients with CKD. These patients are primarily treated by approximately 7,000 nephrologists, and we believe we can reach most of this market with a specialty sales force of approximately 125 people. We intend to seek one or more commercial collaborators for the development and commercialization of AKB-6548 outside of the United States. We may also explore opportunities to expand AKB-6548 into additional markets not adequately addressed by injectable rESAs because of safety or dosing delivery issues, including idiopathic anemia of aging, or IAA, and anemia of congestive heart failure.

We are led by a team of experienced biopharmaceutical executives with a background in developing and commercializing drugs for the treatment of renal and metabolic disorders. John P. Butler, our CEO, was former President of Genzyme Corp.'s renal division which grew to over \$1 billion in annual revenue under his leadership, and is current Chairman of the Board of the American Kidney Fund, the leading patient advocacy organization for kidney disease patients. Earlier in his career, Mr. Butler held sales and marketing positions at Amgen, working on the early commercial launch of injectable rESAs in the renal anemia market. Our executive team also includes Robert Shalwitz, M.D., CMO and co-founder of Akebia. Dr. Shalwitz is an academic pediatric endocrinologist and has extensive industry experience developing novel pharmaceuticals at Abbott Laboratories and Reliant Pharmaceuticals. He has developed extensive knowledge of HIF biology over his career, particularly over the past seven years in leading development at Akebia.

### **Our Strategy**

Our strategy is to develop novel therapeutics for patients based on HIF biology and to commercialize products for patients with kidney disease, beginning with AKB-6548 for patients with anemia secondary to CKD. The key elements of our strategy are to:

- **Complete the development of AKB-6548 for anemia secondary to CKD.** We plan to complete the Phase 2b trial that is currently enrolling in the United States. We intend to initiate a Phase 3 development program in 2015 following our end of Phase 2 meeting with the United States Food and Drug Administration, or FDA.
- **Obtain regulatory approval of AKB-6548 for anemia secondary to CKD in the United States, Europe and other markets.** We plan to complete an end of Phase 2 meeting with the FDA and seek scientific advice from the European Medicines Agency, or EMA, to define the Phase 3 development program necessary to secure regulatory approval to market AKB-6548. We would expect to initiate Phase 3 trials for anemia secondary to CKD in 2015, and would anticipate submitting an NDA for AKB-6548 in the United States by 2018 if the Phase 3 data are favorable.
- **Commercialize AKB-6548 in the United States and other territories.** We will establish a specialty sales and marketing organization to commercialize AKB-6548 in the United States. Outside of the United States, we intend to seek one or more commercial collaborators.
- **Continue to develop AKB-6548 for further indications.** We plan to initiate, in the first half of 2014, a Phase 2 study for AKB-6548 in dialysis patients with anemia, the second indication we intend to pursue. Additionally, we plan to evaluate the product candidate in IAA and other indications.
- **Advance our earlier stage pipeline asset.** We plan to advance AKB-6899, a second HIF-PH inhibitor product candidate, which we believe, based on preclinical testing, has the ability to increase EPO levels while reducing vascular endothelial growth factor, or VEGF, levels. We intend to file an Investigational New Drug, or IND, application and begin Phase 1 trials to determine its potential use in oncology and ophthalmology.
- **Acquire or in-license additional nephrology products.** If we are able to successfully launch AKB-6548, we will look to leverage our commercial infrastructure with additional products that would be prescribed by nephrologists.

We may enter into strategic collaborations to fully realize all of the elements of our strategy.

### **AKB-6548 as a Potential Solution**

We are developing our lead product candidate, AKB-6548, to be a best in class HIF-PH inhibitor for the treatment of anemia secondary to CKD. We expect AKB-6548 to offer:

- Predictable, meaningful and sustained improvements in hemoglobin levels;
- Once a day therapy delivered orally;
- A dosing regimen that restores the normal diurnal EPO pattern;
- Robust pharmacodynamics and substantially lower peak EPO levels than with injectable rESAs; and
- Reduced administration of IV or oral iron supplementation to patients treated for anemia secondary to CKD.

### **Potential Best in Class Profile**

We believe AKB-6548 has compelling clinical data demonstrating a best in class profile with several potential safety and efficacy advantages over current injectable rESA therapy in the treatment of anemia secondary to CKD.

- *AKB-6548 significantly increases hemoglobin in anemic CKD patients.* We have successfully completed a Phase 2a trial, in which AKB-6548 significantly increased hemoglobin levels compared to baseline in a dose-dependent manner across all treatment arms ( $p < 0.0001$ ). Further, AKB-6548 provides a physiologic reticulocyte, or newly formed RBC, response, which leads to a more gradual and consistent increase in hemoglobin levels than what is seen with injectable rESA therapies, meaning that these improvements occur without causing patients' hemoglobin to rise to levels that cause concern.
- *AKB-6548 may have the potential to restore the normal diurnal variation of EPO for a patient with anemia in a way that an injectable rESA cannot.* Instead of binding directly to and saturating the EPO receptor for prolonged periods of time as is the case with current injectable rESA treatments, AKB-6548 acts by simulating the body's natural response to hypoxia that is carried out by stabilization of HIFa.
- *Oral, once-daily dosing.* Once-daily, oral dosing of AKB-6548 offers improved convenience for patients as compared to injectable rESAs. This convenience may increase access to anemia therapy for the largely underserved population of patients with anemia secondary to CKD who are not yet on dialysis and for patients with other forms of anemia, such as idiopathic anemia of aging. AKB-6548 offers the potential of flexible oral dosing that provides a more gradual and reliable means of titration than that of injectable rESAs.
- *Ability to stabilize the iron supply to the bone marrow while improving hemoglobin production.* In clinical trials, AKB-6548 has demonstrated a dose-related increase in total iron binding capacity. These results indicate that AKB-6548 will stabilize the iron supply to the bone marrow while improving hemoglobin production and should improve EPO responsiveness. As a result, unlike injectable rESAs, which have no effect on iron mobilization, AKB-6548 offers the added potential benefit of reducing the amount of supplemental iron required by anemia patients.
- *Differentiated safety profile.* AKB-6548's novel mechanism of action and dosing profile offer the opportunity to potentially avoid the black box label ascribed to injectable rESAs. In our recently completed Phase 2a study, no drug-related serious adverse events were reported. Dosing was well-tolerated and there was no evidence of undesirable vascular response.

### **Risk Associated with Our Business**

An investment in our common stock involves a high degree of risk. Any of the factors set forth under "Risk Factors" may limit our ability to successfully execute our business strategy. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under "Risk Factors" in deciding whether to invest in our common stock. These risk factors include, among others:

- We depend heavily on the success of one product candidate, AKB-6548, which is in a Phase 2b clinical trial. Even if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, AKB-6548.
- We have incurred significant losses since inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We will require substantial additional financing. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

- We have not obtained agreement with the FDA, the EMA or other regulatory authorities on the design of our Phase 3 development program.
- Clinical drug development is a lengthy and expensive process with an uncertain outcome, and positive results from Phase 1 and Phase 2a clinical trials of AKB-6548 are not necessarily predictive of the results of our current Phase 2b and any future clinical trials of AKB-6548. If we cannot replicate the positive results from our Phase 1 and Phase 2a clinical trials of AKB-6548 in our Phase 2b and subsequent clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize AKB-6548.
- Even if we receive regulatory approval for our product candidates, such drug products will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.
- If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market. We are currently involved in an opposition proceeding involving one of our European patents, and the outcome of that proceeding may affect our ability to establish a competitive advantage in the market or successfully commercialize our lead product candidate in the European Union.
- Third-party claims of intellectual property infringement may be costly and time consuming, and may delay or harm our drug discovery and development efforts. We are currently involved in an opposition proceeding involving the granted European patent of one of our potential competitors.

#### **Implications of Being an Emerging Growth Company**

As a company with less than \$1 billion in revenue during our most recently completed fiscal year, we qualify as an “emerging growth company” as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable, in general, to public companies that are not emerging growth companies. These provisions include:

- Reduced disclosure about our executive compensation arrangements;
- Exemption from the non-binding shareholder advisory votes on executive compensation or golden parachute arrangements;
- Exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting; and
- Reduced disclosure of financial information in this prospectus, such as being permitted to include only two years of audited financial information and two years of selected financial information in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure.

We may take advantage of these exemptions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than \$1 billion in annual revenues as of the end of a fiscal year, have more than \$700 million in market value of our capital stock held by non-affiliates as of any June 30 or if we issue more than \$1 billion of non-convertible debt over a three-year-period. We may choose to take advantage of some, but not all, of the available exemptions. We have



taken advantage of some reduced reporting burdens in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

The JOBS Act permits an emerging growth company to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

**Corporate Information**

We were incorporated under the laws of the state of Delaware in February 2007. In December 2011, we spun out our programs focused on the treatment of diabetic eye disease and inflammatory bowel disease into Aerpio Therapeutics, Inc., or Aerpio, which has since operated as a stand-alone company. Our principal executive office is located at 245 First Street, Suite 1100, Cambridge MA 02142, and our telephone number is 617-871-2098. Our website address is *www.akebia.com*. We have included our website address in this prospectus solely as an inactive textual reference. The information on, or that can be accessed through, our website is not part of this prospectus, and you should not rely on any such information in making the decision whether to purchase our common stock.

This prospectus contains trademarks and tradenames of other businesses that are the property of their respective owners. We have omitted the ® and ™ designations, as applicable, for the trademarks named in this prospectus.

**The Offering**

Common stock offered by us	shares
Common stock to be outstanding immediately following this offering	shares
Underwriters' over-allotment option	The underwriters have an option to purchase up to additional shares of common stock to cover over-allotments as described in "Underwriting."
Use of proceeds	<p>We estimate that the net proceeds from the issuance of our common stock in this offering will be approximately \$ million, or approximately \$ million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds from this offering to continue clinical development of AKB-6548 in patients with anemia secondary to CKD, including the preparation for and initiation of the Phase 3 trials; to conduct a Phase 2 clinical trial of AKB-6548 in idiopathic anemia of aging; to advance our preclinical candidate, AKB-6899, through Phase 1 development in oncology; and for working capital and other general corporate purposes. See "Use of Proceeds" for additional information.</p>
Risk factors	See "Risk Factors" and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Proposed NASDAQ Global Market symbol	We have applied for listing of our common stock on the NASDAQ Global Market under the symbol "AKBA."
<p>The number of shares of common stock to be outstanding after this offering is based on 7,648,979 shares of common stock outstanding as of December 31, 2013, including 546,965 shares of restricted stock and 6,858,496 shares of our common stock issuable upon the automatic conversion of all outstanding shares of our preferred stock, and excludes the following:</p> <ul style="list-style-type: none"><li>• 715,085 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2013 at a weighted-average exercise price of \$1.77 per share;</li><li>• 88,633 shares of common stock reserved for future issuance under our Amended and Restated 2008 Equity Incentive Plan as of December 31, 2013; and</li><li>• 1,020,000 shares of common stock reserved for future issuance under our 2014 Incentive Plan.</li></ul>	

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Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- a -for- stock split of our common stock expected to be completed prior to the closing of this offering;
- the amendment and restatement of our certificate of incorporation and bylaws, which will occur immediately prior to the closing of this offering;
- the conversion of all of our outstanding shares of our preferred stock into 6,858,496 shares of common stock, which will occur automatically upon the closing of this offering;
- no exercise of stock options on or after December 31, 2013; and
- no exercise by the underwriters of their option to purchase up to an additional shares of common stock in this offering.

**Summary Financial Data**

The following summary financial data for the years ended December 31, 2012 and 2013, and the period from February 27, 2007 (inception) to December 31, 2013 are derived from our audited financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the captions “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

	Year Ended December 31,		Period from February 27, 2007 (Date of Inception) to December 31, 2013
	2012	2013	2013
(dollars in thousands, except per share data)			
<b>Consolidated statements of operations data:</b>			
Revenue	—	\$ —	\$ —
Expenses:			
Research and development	5,632	10,781	51,748
General and administrative	2,891	5,152	15,269
Total expenses	8,523	15,933	67,017
Loss from operations	(8,523)	(15,933)	(67,017)
Other income, net	327	2,766	3,975
Net loss	\$ (8,196)	\$ (13,167)	\$ (63,042)
Net loss per share applicable to common stockholders—basic and diluted <sup>(1)</sup>	\$ (48.68)	\$ (222.14)	\$ (841.82)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted		310,858	154,875
Pro forma net loss per share applicable to common stockholders—basic and diluted (unaudited) <sup>(1)</sup>		\$ (2.30)	
Pro forma weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted (unaudited)		5,790,016	

- (1) See Note 2 within the notes to our financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share of common stock. Pro forma basic and diluted net loss per share of common stock is calculated by dividing net loss attributable to common stockholders, excluding the impact of gains (losses) on the extinguishment of preferred stock, accretion of preferred stock and including the impact of compensation expense associated with awards of restricted stock that contain a performance condition wherein vesting is contingent upon our consummation of a Liquidity Event, as defined in the Restricted Stock Agreement from the December 23, 2013 grants, by the pro forma weighted-average number of common shares outstanding.

The pro forma balance sheet data set forth below give effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 6,858,496 shares of our common stock upon the closing of this offering.

The pro forma as adjusted balance sheet data set forth below give further effect to our issuance and sale of \_\_\_\_\_ shares of our common stock in this offering at an assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range listed on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

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The pro forma as adjusted information presented in the summary balance sheet data are illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease each of cash and cash equivalents, total assets and total stockholders' deficit on a pro forma as adjusted basis by approximately \$ , assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase or decrease of 1,000,000 shares offered by us at the assumed initial public offering price would increase or decrease each of cash and cash equivalents, total assets and total stockholders' deficit on a pro forma as adjusted basis by approximately \$ , after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of December 31, 2013		Pro forma as adjusted
	Actual	Pro forma (in thousands)	
<b>Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 21,215	\$ 21,215	\$
Working capital	29,529	29,529	
Total assets	34,665	34,665	
Redeemable convertible preferred stock	157,827	—	
Deficit accumulated during the development stage	(127,072)	(63,707)	
Total stockholders' (deficit) equity	(127,072)	30,755	

## Risk Factors

*Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this prospectus, including our financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in our common stock. If any of the following risks actually occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our common stock could decline and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business.*

### **Risks Related to Our Financial Position and Need for Additional Capital**

***We have incurred significant losses since inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.***

We have incurred net losses each year since our inception, including net losses of \$8.2 million for the year ended December 31, 2012, and \$13.2 million for the year ended December 31, 2013. As of December 31, 2013, we had an accumulated deficit of \$127.1 million. To date, we have not commercialized any products or generated any revenues from the sale of products, and we do not expect to generate any product revenues in the foreseeable future. We do not know whether or when we will generate revenue or become profitable.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through private placements of our preferred stock. The amount of our future net losses will depend, in part, on the rate of our future expenditures, and our financial position will depend, in part, on our ability to obtain funding through equity or debt financings, strategic collaborations or grants. Our lead product candidate, AKB-6548, is currently in an ongoing Phase 2b clinical trial, and our other product candidate is in preclinical development. As a result, we expect that it will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market AKB-6548, our future revenues will depend upon the size of any markets in which AKB-6548 has received approval, our ability to achieve sufficient market acceptance, reimbursement from third-party payors and other factors.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue our Phase 2b trial and prepare for a future Phase 3 development program of AKB-6548 for the treatment of anemia secondary to CKD;
- seek regulatory approvals for our product candidates that successfully complete clinical studies;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- initiate additional preclinical, clinical or other studies for AKB-6548, AKB-6899 and other product candidates that we may develop or acquire;
- seek to discover and develop additional product candidates;
- acquire or in-license other commercial products, product candidates and technologies;
- make royalty, milestone or other payments under any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and

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- create additional infrastructure to support our operations as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, if at all, we will be able to achieve profitability. If we are required by the United States Food and Drug Administration, or FDA, the EMA or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

To become and remain profitable, we must succeed in developing and commercializing our product candidates, which must generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

***We will require substantial additional financing. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.***

As of December 31, 2013, our cash and cash equivalents were \$21.2 million. We believe that we will continue to expend substantial resources for the foreseeable future developing AKB-6548, AKB-6899 and any other product candidates that we may develop or acquire. These expenditures will include costs associated with research and development, potentially obtaining regulatory approvals and having our products manufactured, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise. Because the outcome of our current and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- the rate of progress, results and cost of completing our Phase 2b clinical trial of AKB-6548 and our operating costs incurred as we conduct these trials and through our end of Phase 2 meeting with the FDA, and equivalent meetings with the EMA and other regulatory authorities;
- assuming AKB-6548 advances to Phase 3 clinical trials, the scope, size, rate of progress, results and costs of initiating and completing our Phase 3 development program of AKB-6548;
- assuming favorable clinical results, the cost, timing and outcome of our efforts to obtain marketing approval for AKB-6548 in the United States, Europe and in other jurisdictions, including to fund the preparation and filing of regulatory submissions for AKB-6548 with the FDA, the EMA and other regulatory authorities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for AKB-6899 and any other product candidates that we may develop or acquire;

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- the timing of, and the costs involved in, obtaining regulatory approvals for AKB-6899 if clinical trials are successful;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of having our product candidates manufactured for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation; and
- the extent to which we acquire or in-license other products or technologies.

Based on our current operating plan, we believe that the net proceeds we receive from this offering, and our existing cash and cash equivalents and investments will be sufficient to fund our projected operating expenses and capital expenditure requirements through at least . However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for AKB-6548, AKB-6899 or any other product candidates that we develop or acquire, or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to product candidates on unfavorable terms to us.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings and license, development and commercialization agreements with collaborators. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, future revenue streams, research programs or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for AKB-6548, AKB-6899 or any other product candidates that we develop or acquire, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.



***Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We commenced active operations in 2007, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, identifying potential product candidates, undertaking preclinical studies and conducting clinical trials. We currently have two product candidates, one of which is in preclinical development. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Only a small fraction of biopharmaceutical development programs ultimately result in commercial products or even product candidates and a number of events could delay our development efforts and negatively impact our ability to obtain regulatory approval for, and to manufacture, market and sell, a drug product. We have not yet demonstrated our ability to successfully complete later stage clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities.

**Risks Related to Our Business and the Clinical Development, Regulatory Review and Approval of AKB-6548 and AKB-6899**

***We depend heavily on the success of one product candidate, AKB-6548, which is in a Phase 2b clinical trial. Even if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize, AKB-6548.***

We currently have only one product candidate, AKB-6548, in clinical development, and our business depends almost entirely on the successful clinical development, regulatory approval and commercialization of that product candidate, which may never occur. We currently have no drug products for sale, generate no revenues from sales of any drugs, and may never be able to develop marketable drug products. AKB-6548, which is currently in an ongoing Phase 2b clinical trial, will require substantial additional clinical development, testing, manufacturing process development, and regulatory approval before we are permitted to commence its commercialization. Our other product candidate, AKB-6899, is in preclinical development. None of our product candidates has advanced into a pivotal study, and it may be years before such study is initiated, if ever. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and, if approved, market any product candidates. Before obtaining regulatory approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical testing and clinical trials that the product candidate is safe and effective for use in each target indication. This process can take many years. Of the large number of drugs in development in the United States, only a small percentage successfully complete the FDA regulatory approval process and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and clinical programs, we may be unable to successfully develop or commercialize AKB-6548.

We are not permitted to market AKB-6548 in the United States until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. As a condition to submitting an NDA to the FDA for AKB-6548 regarding its ability to treat patients with anemia secondary to CKD, we must complete our ongoing Phase 2b clinical trial, Phase 3 studies, and any additional non-clinical or clinical studies required by the FDA. To date, we have only commenced the Phase 2b clinical trial. AKB-6548 may not be successful in clinical trials or receive regulatory approval. Further, AKB-6548 may not receive regulatory approval even if it is successful in clinical trials. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process that typically takes many years following the commencement of clinical trials

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and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, the safety concerns associated with injectable rESAs and the black box warnings in their prescribing information may affect the FDA's review of the safety results of AKB-6548. Further, the policies or regulations, or the type and amount of clinical data necessary to gain approval, may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that AKB-6548 will never obtain regulatory approval. The FDA may delay, limit or deny approval of AKB-6548 for many reasons, including, among others:

- we may not be able to demonstrate that AKB-6548 is safe and effective in treating anemia secondary to CKD to the satisfaction of the FDA;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not approve the formulation, labeling or specifications of AKB-6548;
- the FDA may require that we conduct additional clinical trials;
- the contract research organizations, or CROs, that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials;
- we may fail to perform in accordance with the FDA's good clinical practice, or GCP, requirements;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA may not approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the policies or regulations of the FDA may significantly change in a manner that renders our clinical data insufficient for approval, or requiring that we amend or submit new clinical protocols.

In addition, similar reasons may cause the EMA or other regulatory authorities to delay, limit or deny approval of AKB-6548 outside the United States.

Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market AKB-6548. Because our business is almost entirely dependent upon AKB-6548, any such setback in our pursuit of regulatory approval would have a material adverse effect on our business and prospects.

Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as we intend or desire or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional, unanticipated clinical trials to obtain approval or be subject to additional post marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product or the FDA may require a risk evaluation and mitigation strategy, or REMS, for a product, which could impose restrictions on its distribution. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

### ***We have not obtained agreement with the FDA, EMA or other regulatory authorities on the design of our Phase 3 development program.***

As we have not completed our Phase 2b clinical trial, we have not obtained agreement with the FDA on the design of our Phase 3 development program. We plan to hold an end of Phase 2 meeting with the FDA upon successful completion of our Phase 2b clinical trial. If the FDA determines that the Phase 2b trial results do not support moving into a pivotal program, we would be required to conduct additional Phase 2 studies. Alternatively, the FDA could disagree with our proposed design of our Phase 3 development program and could

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suggest a larger number of subjects or a longer course of treatment than our current expectations. If the FDA takes such positions, the costs of our AKB-6548 development program could increase materially and the potential market introduction of AKB-6548 could be delayed or we could risk not obtaining FDA approval even if the Phase 3 trials meet their primary endpoints. The FDA also may require that we conduct additional clinical, nonclinical or manufacturing validation studies and submit that data before it will consider an NDA application.

We have not yet sought guidance for the regulatory path for AKB-6548 with the EMA or other regulatory authorities. We cannot predict what additional requirements may be imposed by these regulatory authorities or how such requirements might delay or increase costs for our planned Phase 3 development program. Because our business is almost entirely dependent upon the successful development, regulatory approval, and commercialization of AKB-6548, any such delay or increase costs would have an adverse effect on our business.

### ***We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our product candidates.***

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends on the speed at which we can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in our clinical trials for AKB-6548 because of negative publicity from adverse events observed in injectable rESAs, other investigational agents and commercial products in CKD or for other reasons, including competitive clinical studies for similar patient populations. In addition, patients controlling their disease with current injectable rESAs may be reluctant to participate in a clinical trial with an investigational drug. As a result, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our development of AKB-6548 or termination of the clinical studies altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics to achieve diversity in a study, to complete our clinical studies in a timely manner. Patient enrollment is affected by factors including:

- severity of the disease under investigation;
- design of the study protocol;
- size and nature of the patient population;
- eligibility criteria for and design of the study in question;
- perceived risks and benefits of the product candidate under study;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies and clinicians' and patients' perceptions as to the potential advantages of AKB-6548 in relation to available therapies or other products under development;
- efforts to facilitate timely enrollment in clinical studies;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate on-going or planned clinical studies, any of which would have an adverse effect on our business.

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***We may not be able to comply with requirements of foreign jurisdictions in conducting trials outside of the United States. In addition, we may not be able to obtain regulatory approval in foreign jurisdictions.***

We currently expect to seek regulatory approval for AKB-6548 for the treatment of anemia secondary to CKD in major markets outside the United States, including the European Union. Our ability to successfully initiate, enroll and complete a clinical study in any foreign country, should we attempt to do so, is subject to numerous risks unique to conducting business in international markets, including:

- difficulty in establishing or managing relationships with qualified CROs and physicians;
- different local standards for the conduct of clinical studies;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments; and
- the acceptability of data obtained from studies conducted in the United States to the EMA and other regulatory authorities.

If we fail to successfully meet requirements for the conduct of clinical trials outside of the United States, we may be delayed in obtaining, or be unable to obtain, regulatory approval for AKB-6548 in countries outside of the United States.

Regulatory authorities outside the United States will require compliance with numerous and varying regulatory requirements. The approval procedures vary among jurisdictions and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a drug product must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our drug product is also subject to approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our drug products in any market.

***Clinical drug development is a lengthy and expensive process with an uncertain outcome, and positive results from Phase 1 and Phase 2a clinical trials of AKB-6548 are not necessarily predictive of the results of our current Phase 2b and any future clinical trials of AKB-6548. If we cannot replicate the positive results from our Phase 1 and Phase 2a clinical trials of AKB-6548 in our Phase 2b and subsequent clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize AKB-6548.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies may not be predictive of similar results in humans during clinical trials, and successful results from early or small clinical trials may not be replicated in later and larger clinical trials. For example, our early encouraging preclinical and clinical results for AKB-6548 do not ensure that the results of our ongoing Phase 2b clinical trial or any future clinical trials will demonstrate similar results. Our current Phase 2b clinical trial and our planned Phase 3 development program will enroll a larger number of subjects and will treat subjects for longer periods than our prior trials, which will result in a greater likelihood that adverse events may be observed. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early stage development, and we may face similar setbacks. If the results of our ongoing or future clinical trials for AKB-6548 are inconclusive with respect to efficacy, if we do not meet our clinical endpoints

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with statistical significance, or if there are safety concerns or adverse events, we may be prevented from or delayed in obtaining marketing approval for AKB-6548.

***We may experience delays in our ongoing Phase 2b clinical trial for AKB-6548 and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all.***

Clinical trials can be delayed or aborted for a variety of reasons, including delay or failure to:

- obtain regulatory approval to commence a clinical trial;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtain institutional review board, or IRB, approval at each site;
- recruit, enroll and retain patients through the completion of clinical trials;
- maintain clinical sites in compliance with trial protocols through the completion of clinical trials;
- address any patient safety concerns that arise during the course of the trial;
- initiate or add a sufficient number of clinical trial sites; or
- manufacture sufficient quantities of our product candidate for use in clinical trials.

We could encounter delays if a clinical trial is suspended or terminated by us, by the relevant IRBs at the sites at which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, changes in laws or regulations, or lack of adequate funding to continue the clinical trial. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Even if we receive regulatory approval for our product candidates, such drug products will be subject to ongoing regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the drug product. In addition, if the FDA approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current Good Manufacturing Practice, or cGMP, requirements and GCP requirements for any clinical trials that we conduct post-approval.

Post-approval discovery of previously unknown problems with an approved drug product, including adverse events of unanticipated severity or frequency or relating to manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the drug product, withdrawal of the drug product from the market, or drug product recalls;

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- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- a REMS program; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

### **Risks Related to Our Reliance on Third Parties**

***We rely on third parties to conduct preclinical studies and clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us, we may not be able to obtain regulatory approvals for our product candidates.***

We rely on third party CROs and other third parties to assist in managing, monitoring and otherwise carrying out our ongoing Phase 2b trial of AKB-6548. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators to conduct our clinical trials in the future, including our Phase 3 development program for AKB-6548. We compete with many other companies for the resources of these third parties. The third parties on whom we rely may terminate their engagements with us at any time, and having to enter into alternative arrangements would delay development and commercialization of our product candidates.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, the FDA and foreign regulatory authorities require compliance with regulations and standards, including GCP requirements, for designing, conducting, monitoring, recording, analyzing and reporting the results of clinical trials to ensure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct our clinical trials, we are responsible for ensuring that each of these clinical trials is conducted in accordance with its general investigational plan and protocol under legal and regulatory requirements. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with clinical trial protocols or meet expected deadlines, the clinical trials of our product candidates may not meet regulatory requirements. If clinical trials do not meet regulatory requirements or if these third parties need to be replaced, preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.

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We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

***We intend to rely on third parties to conduct some or all aspects of our product manufacturing, and these third parties may not perform satisfactorily.***

We do not have any manufacturing facilities and do not expect to independently conduct our product candidate manufacturing for research and preclinical and clinical testing. We currently rely, and expect to rely, on third parties to manufacture and supply drug products for our AKB-6548 clinical trials, and we expect to continue to rely on third parties for the manufacture of clinical and, if necessary, commercial quantities of our product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

Any of these third parties may terminate their engagement with us at any time. We believe we have sufficient drug product to complete our ongoing Phase 2b trial of AKB-6548. On February 28, 2014, we entered into an agreement with Evonik Corporation, or Evonik, for the manufacturing of the drug substance for the Phase 3 development program of AKB-6548. If Evonik cannot perform as agreed, we may be required to find replacement manufacturers. We also do not currently have arrangements in place for the manufacturing of drug product for the Phase 3 development program. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur significant delays and added costs in identifying, qualifying and contracting with any such replacement, as well as producing the drug product. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays. These delays could result in a suspension of our clinical trials or, if AKB-6548 is approved and marketed, a failure to satisfy patient demand.

Reliance on third party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- reduced control as a result of using third party manufacturers for all aspects of manufacturing activities, including regulatory compliance and quality assurance;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- disruptions to the operations of our manufacturers or suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or a catastrophic event affecting our manufacturers or suppliers.

Any of these events could lead to clinical study delays or failure to obtain regulatory approval, or affect our ability to successfully commercialize future products. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with

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cGMP requirements for manufacture of both drug substance and finished drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or other regulatory authorities do not approve these facilities for the manufacture of our product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Moreover, our failure, or the failure of our third party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products or product candidates.

In addition, our product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. Certain of these manufacturing facilities may be contractually prohibited from manufacturing our product due to non-compete agreements with our competitors. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

***If we are unable to manufacture our product candidates in sufficient quantities, at sufficient yields, we may experience delays in product development, clinical trials, regulatory approval and commercial distribution.***

Completion of our clinical trials and commercialization of our product candidates require access to, or development of, facilities to manufacture our product candidates at sufficient yields and at commercial scale. We have limited experience manufacturing, or managing third parties in manufacturing, any of our product candidates in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality.

Our reliance on contract manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture our bulk drug product on a commercial scale, replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of our drug product. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale-up and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations that vary in each country where a product might be sold; and
- lack of capital funding.

Any delay or interruption in our supply of product candidates could have a material adverse effect on our business, financial condition, results of operations and cash flows.



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***We may not be successful in establishing and maintaining strategic collaborations, which could adversely affect our ability to develop and commercialize our product candidates, negatively impacting our operating results.***

We plan to commercialize AKB-6548 ourselves in the United States and will likely seek one or more strategic collaborators to commercialize AKB-6548 in additional markets. We face competition in seeking appropriate collaborators for our product candidates, and the negotiation process is time-consuming and complex. In order for us to successfully collaborate with a third party on our product candidates, potential collaborators must view these product candidates as economically valuable. Even if we are successful in our efforts to establish strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product is delayed or sales of an approved product are disappointing. Any delay in entering into strategic collaboration agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

In addition, our strategic collaborators may terminate any agreements they enter into with us, and we may not be able to adequately protect our rights under these agreements. Furthermore, our strategic collaborators will likely negotiate for certain rights to control decisions regarding the development and commercialization of our product candidates, if approved, and may not conduct those activities in the same manner as we do.

If we fail to establish and maintain strategic collaborations related to our product candidates, we will bear all of the risk and costs related to the development and commercialization of any such product candidate, and we may need to seek additional financing, hire additional employees and otherwise develop expertise. This could negatively affect the development of any unpartnered product candidate.

### **Risks Related to Our Intellectual Property**

***If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market. We are currently involved in an opposition proceeding involving one of our European patents, and the outcome of that proceeding may affect our ability to establish a competitive advantage in the market or successfully commercialize our lead product candidate in the European Union.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

In July of 2011, a third party filed an opposition to one of our issued European patents, European Patent No. 2044005, which we refer to as the '005 Patent. During the oral proceedings, which took place on April 10, 2013, the Opposition Division of the European Patent Office decided to maintain certain claims of the patent directed to a compound chosen from a group of eight compounds, including AKB-6548, as well as claims to compositions and methods for treating various diseases, including, but not limited to anemia. Both parties have appealed the decision of the Opposition Division and final resolution of the opposition proceeding will likely take a number of years. We cannot be assured of the breadth of the claims that will remain in the '005 Patent or that the patent will not be revoked in its entirety. If the European Patent Office decides to narrow the scope of the claims or revoke the '005 Patent, we may not be able to establish a competitive advantage in the European Union in our market or successfully commercialize our lead product candidates in the European Union, which could materially adversely affect our business, operating results and financial condition.

Composition-of-matter patents on the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. Method-of-use patents protect the use of a product for the specified method.

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This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, inventorship, or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third-party or instituted by the USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2011), which brings into effect significant changes to the U.S. patent laws and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a “first to file” system in the United States. This will require us to be cognizant of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

***Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.***

Because we rely on third parties to research and develop and to manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information

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increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

***Third-party claims of intellectual property infringement may be costly and time consuming, and may delay or harm our drug discovery and development efforts. We are currently involved in an opposition proceeding involving the granted European patent of one of our potential competitors.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. The pharmaceutical and biotechnology industries are characterized by extensive litigation over patent and other intellectual property rights. We may become a party to, or threatened with, future adversarial litigation or other proceedings regarding intellectual property rights with respect to our drug candidates. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our drug candidates may give rise to claims of infringement of the patent rights of others.

While our product candidates are in preclinical studies and clinical trials, we believe that the use of our product candidates in these preclinical studies and clinical trials in the United States falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e), which provides that it shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention solely for uses reasonably related to the development and submission of information to the FDA. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. We attempt to ensure that our product candidates and the methods we employ to manufacture them, as well as the methods for their use we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

Third parties may hold or obtain patents or other intellectual property rights and allege in the future that the use of our product candidates infringes these patents or intellectual property rights, or that we are employing their proprietary technology without authorization. For example, we are aware of certain patents that have been acquired by FibroGen, Inc., or FibroGen, directed to certain heterocyclic carboxamide compounds that are described as inhibitors of prolyl-4-hydroxylase. Those patents, however, expire as of December 2014, absent extension, before we anticipate receiving regulatory approval for our product candidates. In addition, we are aware of subsequent U.S. patents issued to FibroGen directed to purportedly new methods of using such previously known heterocyclic carboxamide compounds for purposes of treating or affecting specified conditions. We do not believe these currently issued FibroGen U.S. patents conflict with our intellectual property rights; nor do we make any admission that any of such patents are valid or enforceable. Under U.S. law, a party may be able to patent a discovery of a new way to use a previously known compound, even if such compound

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itself is patented, provided the newly discovered use is novel and nonobvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method. We are not aware of any valid U.S. patents issued to FibroGen that claim methods of using any of our product candidates for purposes of inhibiting hypoxia-inducible factor prolyl-hydroxylases, or HIF-PHs, for the treatment of anemia secondary to CKD. In June 2013, the European Patent Office granted European Patent No. 1463823, or the '823 patent, to FibroGen. The '823 patent claims, among other things, the use of a heterocyclic carboxamide compound selected from the group consisting of pyridine carboxamides, quinoline carboxamides, isoquinoline carboxamides, cinnoline carboxamides, and beta-carboline carboxamides that inhibits HIF-PH enzyme activity in the manufacture of a medicament for increasing endogenous EPO in the prevention, pretreatment or treatment of anemia. On December 5, 2013, we filed an opposition to the '823 patent requesting that the '823 patent be revoked in its entirety. While, for the reasons set forth in our opposition, we believe the '823 patent should be revoked in its entirety, the ultimate outcome of the opposition remains uncertain. If the European Patent Office decides not to revoke the '823 patent in its entirety, or only certain claims of the '823 patent, and any surviving claims are determined to encompass our intended use of our lead product candidate, we may not be able to commercialize our lead product candidate in the European Union for its intended use, which could materially adversely affect our business, operating results and financial condition. FibroGen has filed patent applications related to the '823 patent in the United States and in other countries, and some of these applications have since issued as patents outside of the U.S. FibroGen is also pursuing other patent applications in the United States and other countries, and some of these have issued as patents. To the extent any such patents issue or have been issued, we may initiate opposition or other legal proceedings with respect to those patents.

There may be patents of third parties, including FibroGen, of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Also, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. Notwithstanding the above, third parties, including FibroGen, may in the future claim that our product candidates and other technologies infringe upon these patents and may file suit against us.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize AKB-6548 or AKB-6899. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or our intended methods of use, including patient selection methods, the holders of any such patent may be able to block or impair our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. We may also elect to enter into a license in order to settle litigation or in order to resolve disputes prior to litigation. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. Should a license to a third party patent become necessary, we cannot predict whether we would be able to obtain a license, or if a license were available, whether it would be available on commercially reasonable terms. If such a license is necessary and a license under the applicable patent is unavailable on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Further, defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim

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of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties or redesign our products, which may be impossible or require substantial time and monetary expenditure.

***We are currently involved in opposition proceedings and may in the future be involved in lawsuits or administrative proceedings to protect or enforce our patents, which could be expensive, time consuming, and unsuccessful.***

We are currently involved in two opposition proceedings in the European Patent Office. These proceedings may be ongoing for a number of years and may involve substantial expense and diversion of employee resources from our business. For more information, see the other risk factors under “—Risks Related to Intellectual Property.”

Competitors may infringe our patents or misappropriate our trade secrets or confidential information. To counter infringement or unauthorized use, we may be required to file infringement or misappropriation claims, which can be expensive and time-consuming. We may not be able to prevent infringement of our patents or misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. In addition, there may be a challenge or dispute regarding inventorship or ownership of patents or applications currently identified as being owned by or licensed to us. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Various administrative proceedings are also available for challenging patents, including interference, reexamination, *inter partes* review, and post-grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. Even if we are successful, participation in interference or other administrative proceedings before the USPTO or a foreign patent office may result in substantial costs and distract our management and other employees.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and some administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment (such as annuities) and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in

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abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We have received confidential and proprietary information from collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and further, may infringe our patents in territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign countries could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

**Risks Related to Commercialization**

***Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors and others in the medical community.***

Even if we obtain marketing approval for AKB-6548, AKB-6899 or any other product candidates that we may develop or acquire in the future, these product candidates may not gain market acceptance among physicians, third-party payors, patients and others in the medical community. In addition, market acceptance of any approved products depends on a number of other factors, including:

- the efficacy and safety of the product, as demonstrated in clinical trials;
- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any warnings that may be required on the label;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the availability of adequate coverage and reimbursement by third party payors and government authorities;
- the ability to contract with dialysis providers;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts; and
- the restrictions on the use of our products together with other medications, if any.

For example, two of the largest operators of dialysis clinics in the United States, DaVita and Fresenius, account for more than half of the injectable rESA sales in the U.S. dialysis market and have entered into long-term sales agreements with Amgen that began in January 2012. We believe that it may be challenging to enter into or expand upon long or short-term supply agreements with DaVita, Fresenius or other operators of dialysis clinics.

Market acceptance is critical to our ability to generate significant revenue. In addition, any product candidate, if approved and commercialized, may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate significant revenue and our business would suffer.

***If we are unable to establish sales, marketing and distribution capabilities or to enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.***

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform these services.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force are expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- our inability to effectively manage geographically dispersed sales and marketing team;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and have to enter into arrangements with third parties to perform these services, our profitability, if any, is likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

***Coverage and reimbursement may be limited or unavailable in certain market segments for any approved products, which could make it difficult for us to sell our products profitably.***

Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third-party payors and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors decide which drugs they will pay for and establish formularies and reimbursement levels. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. Additionally, we may be required to enter into contracts with third-party payors to obtain favorable formulary status. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Even if we obtain coverage for our product candidates, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for, or the price of, our products. If reimbursement is not available or is available only to limited levels, we may not be able to commercialize certain of our products. In addition, in the United States third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs. As a result, significant uncertainty exists as to whether and how much third-party payors will reimburse patients for their use of newly approved drugs, which in turn will put pressure on the pricing of drugs.

In addition, if AKB-6548 is used in an outpatient dialysis facility, such facilities often receive fixed reimbursement for all dialysis services furnished to patients with end-stage renal disease, or ESRD. For example, Medicare payments to ESRD facilities for such services are based on a prospective payment system known as the



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basic case-mix adjusted composite payment system. These payments cover a bundle of items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home, including the cost of certain routine drugs such as our product candidates. Patient and treatment provider access to adequate coverage and reimbursement by government and private insurance plans is central to the acceptance of any products for which we receive regulatory approval. We may be unable to sell AKB-6548, if approved, to dialysis providers on a profitable basis if third-party payors reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.

### ***Price controls may be imposed, which may adversely affect our future profitability.***

In some countries, particularly member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

### ***The impact of recent healthcare reform and other changes in the healthcare industry and in healthcare spending is currently unknown, and may adversely affect our business model.***

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to reduce costs. For example, the Centers for Medicare and Medicaid Services, or CMS, has enacted regulations that reduced capitated payments to dialysis providers. These cost reduction initiatives and other provisions of this legislation could decrease the scope of coverage and the price that we receive for any approved products and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policies and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may cause a similar reduction in payments from private payors. Similar regulations or reimbursement policies may be enacted in international markets which could similarly impact our business.

In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively PPACA, was enacted in 2010 with a goal of reducing the cost of healthcare and substantially changing the way healthcare is financed by both government and private insurers. The PPACA, among other things, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations,

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establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. In addition, other legislative changes have been proposed and adopted in the United States since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any drug products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

***If our product candidates obtain marketing approval, we will be subject to healthcare laws, regulation and enforcement and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.***

If we obtain approval for any of our product candidates and begin commercializing them, our operations may be directly, or indirectly through our customers, subject to additional healthcare regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security, and transmission of individually identifiable health information;
- the federal physician sunshine requirements under PPACA, which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the CMS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and

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ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reforms have strengthened these laws. For example, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. The PPACA also amended the False Claims Act, such that violations of the anti-kickback statute are now deemed violations of the False Claims Act. To constitute a false claim prior to this amendment, an anti-kickback violation had to be accompanied by a false statement, such as false certification of compliance.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results.

***We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than we do.***

The development and commercialization of new drug products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the development and commercialization of our product candidates. Our objective is to develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we commercialize will compete with existing, market-leading products.

If AKB-6548 is approved and launched commercially, competing drugs may include EPOGEN and Aranesp, commercialized by Amgen, Procrit and Eprex, commercialized by Johnson & Johnson, and Mircera, commercialized by Roche outside of the United States. We may face competition from potential new anemia therapies. There are several other HIF product candidates in various stages of active development for anemia indications that may be in direct competition with AKB-6548 if and when it is approved and launched commercially. These candidates are being developed by such companies as FibroGen/AstraZeneca, Japan Tobacco, GlaxoSmithKline and Bayer. FibroGen, in particular, is currently in Phase 3 clinical development of its product candidate, FG-4592 (roxadustat). Some of these product candidates may enter the market as early as 2017. In addition, certain companies are developing potential new therapies for renal-related diseases that could potentially reduce rESA utilization and thus limit the market for AKB-6548 if and when it is approved and launched commercially.

Since rESAs are biologic products, the introduction of biosimilars into the rEPO market in the United States will constitute additional competition for AKB-6548 if we are able to obtain approval for and commercially launch our product. A biosimilar product is a follow-on version of an existing, branded biologic product. The patents for the existing, branded product must expire in a given market before biosimilars may enter that market without risk

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of being sued for patent infringement. In addition, an application for a biosimilar product cannot be approved by the FDA until 12 years after the existing, branded product was approved under a Biologics License Application, or BLA. The patents for epoetin alfa, a version of rEPO, expired in 2004 in the European Union, and the remaining patents have expired or will expire between 2012 and 2015 in the United States. Several biosimilar versions of rEPO are available for sale in the European Union and biosimilar versions of rEPO are currently being studied in clinical trials in the United States.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. Large and established companies such as Amgen and Roche, among others, compete in the market for drug products to treat anemia. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their research and development efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products before, or more effectively than, we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

### ***Our products may cause undesirable side effects or have other properties that delay or prevent their regulatory approval or limit their commercial potential.***

Undesirable side effects caused by our products or even competing products in development that utilize a common mechanism of action could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities and potential products liability claims. We are currently conducting a Phase 2b clinical trial for AKB-6548. Serious adverse events deemed to be caused by our product candidates could have a material adverse effect on the development of our product candidates and our business as a whole. The most common drug-related adverse events to date in the clinical trial evaluating the safety and tolerability of AKB-6548 have been gastro-intestinal disorders. Our understanding of the relationship between AKB-6548 and these events, as well as our understanding of adverse events in future clinical trials of other product candidates, may change as we gather more information, and additional unexpected adverse events may be observed.

If we or others identify undesirable side effects caused by our product candidates either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- patient recruitment could be slowed, or enrolled patients may not want to complete a clinical trial;
- we may be unable to obtain regulatory approval for our product candidates or regulatory authorities may withdraw approvals of product candidates;
- regulatory authorities may require additional warnings on the label;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

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Any of these events could prevent us from achieving or maintaining market acceptance of our products and could substantially increase commercialization costs.

### **Risks Related to Our Business and Industry**

***If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop our products, conduct our clinical trials and commercialize our product candidates.***

We are highly dependent on members of our senior management, including John Butler, our President and Chief Executive Officer and Robert Shalwitz, our Chief Medical Officer. The loss of the services of either of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. We may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel.

In addition, certain of our current employees, including Dr. Shalwitz, our Chief Medical Officer, also provide services to Aerpio Therapeutics, Inc., or Aerpio, a company we spun out in 2011, under a services agreement between Akebia and Aerpio. As a result, these employees devote some of their time to activities relating to Aerpio's business. For example, Dr. Shalwitz is expected to spend approximately 5% of his time providing services to Aerpio. In addition, some of our employees who provide services to Aerpio may ultimately become full-time employees of Aerpio and we will be forced to hire additional personnel to replace them.

We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (1) FDA regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (2) manufacturing standards, (3) federal and state healthcare fraud and abuse laws and regulations, or (4) laws that require the reporting of true and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or

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asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

### ***We may encounter difficulties in managing our growth and expanding our operations successfully.***

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our future financial performance and our ability to commercialize AKB-6548, if approved, and any other product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

### ***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any product candidates that we may develop; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance covering our clinical trials in the amount of \$10 million in the aggregate. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in

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excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

***If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

***We may not be able to win government, academic institution or non-profit contracts or grants.***

From time to time, we may apply for contracts or grants from government agencies, non-profit entities and academic institutions. Such contracts or grants can be highly attractive because they provide capital to fund the on-going development of our product candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for or to otherwise be eligible to receive certain contracts or grants that our competitors may be able to satisfy that we cannot. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants will be awarded and the size of the contracts or grants to each awardee. Even if we are able to satisfy the award requirements, there is no guarantee that we will be a successful awardee. Therefore, we may not be able to win any contracts or grants in a timely manner, if at all.

### **Risks Related to Our Common Stock and This Offering**

***We are eligible to be treated as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our common stock less attractive to investors.***

We are an "emerging growth company", as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

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- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Investors may find our common stock less attractive if we continue to rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We could be an emerging growth company for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non-affiliates exceeds \$700 million as of any June 30 before that time or if we have total annual gross revenue of \$1 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” if the market value of our common stock held by non-affiliates is below \$75 million as of June 30 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including exemption from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

***We do not know whether a market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for you to sell your shares of our common stock.***

Before this offering, there was no public trading market for our common stock. If a market for our common stock does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price, or at all. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborators or acquire companies or products by using our shares of common stock as consideration. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.



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***The market price of our common stock may be highly volatile, and you may not be able to resell your shares at or above the initial public offering price.***

The initial public offering price for our shares will be determined by negotiations between us and the representatives of the underwriters and may not be indicative of prices that will prevail in the trading market. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of clinical trials of our product candidates;
- the timing of the release of results of our clinical trials;
- results of clinical trials of our competitors' products;
- safety issues with respect to our products or our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- changes in market conditions for biopharmaceutical stocks; and
- changes in general market and economic conditions.

In addition, the stock market has recently experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.***

As of December 31, 2013, our executive officers, directors and principal stockholders, together with their respective affiliates, owned approximately 80% of our common stock, including shares subject to outstanding options that are exercisable within 60 days after such date, and we expect that upon completion of this offering that same group will continue to hold at least % of our outstanding common stock. Accordingly, even after this offering, these stockholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring stockholder approval, including the election of our board of directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or the board of directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our common stock.

***A significant portion of our total outstanding shares may be sold into the public market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time after the expiration of the lock-up agreements described in the “Underwriting” section of this prospectus. These sales, or the market perception that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have shares of common stock outstanding. This includes the shares that we are selling in this offering, which may be resold in the public market immediately subject to any restrictions imposed on our affiliates under Rule 144. The remaining shares, or % of our outstanding shares after this offering, are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold, subject to any applicable volume limitations under federal securities laws with respect to affiliate sales, in the near future as set forth below.

In addition, as of December 31, 2013, there were 715,085 shares subject to outstanding options that will become eligible for sale in the public market to the extent permitted by any applicable vesting requirements, the lock-up agreements and Rules 144 and 701 under the Securities Act. Moreover, after this offering, holders of an aggregate of 7,602,743 shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If such holders, by exercising their registration rights, cause a large number of securities to be registered and sold into the public market, these sales could have an adverse effect on the market price for our common stock. We also intend to register all shares of common stock that we may issue under our employee benefit plans, including our 2014 Incentive Plan. Once we register these shares and they are issued in accordance with the terms of the plans, they can be freely sold in the public market upon issuance, subject to the lock-up agreements and the restrictions imposed on our affiliates under Rule 144. For more information, see “Shares Eligible for Future Sale—Rule 144”.

***You will incur immediate and substantial dilution as a result of this offering.***

The initial public offering price of our common stock will be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase common stock in this offering, you will pay a price per share that substantially exceeds our pro forma adjusted net tangible book value per share after this offering. To the extent shares subsequently are issued under options, you will incur further dilution. Based on an initial public offering price of \$ , the midpoint of the range set forth on the cover page of this prospectus, you will incur immediate and substantial dilution of \$ per share, representing the difference between our pro forma net tangible book value per share, after giving effect to this offering, and the assumed initial public offering price. In addition, purchasers of common stock in this offering will have contributed approximately % of the aggregate price paid by all purchasers of our stock but will own approximately % of our common stock outstanding after this offering.

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### ***We have broad discretion in the use of net proceeds from this offering and may not use them effectively.***

We currently intend to use the net proceeds from this offering for continuing clinical development of AKB-6548 in patients with anemia secondary to CKD, including the preparation for and initiation of the Phase 3 trials, for conducting a Phase 2 clinical trial of AKB-6548 in idiopathic anemia of aging, or IAA, for advancing AKB-6899 through Phase 1 development in oncology and for working capital and other general corporate purposes. See the section of this prospectus entitled “Use of Proceeds.” Although we currently intend to use the net proceeds from this offering in such a manner, we will have broad discretion in the application of the net proceeds. Our failure to apply these funds effectively could affect our ability to continue to develop and commercialize our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or loses value.

### ***We will incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.***

As a public company, we will incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management’s time and attention from product development activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with this offering, we are increasing our directors’ and officers’ insurance coverage, which will increase our insurance cost. In the future, it will be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

In addition, in order to comply with the requirements of being a public company, we may need to undertake various actions, including implementing new internal controls and procedures and hiring new accounting or internal audit staff. The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934 as amended, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our ordinary shares could decline. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on NASDAQ.

We are not currently required to comply with the SEC’s rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not yet required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Upon becoming a public company, we will be required to comply with certain of these rules, which will require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our second annual report. This assessment will need to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate

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internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statement.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the later of our second annual report or the first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company” as defined in the JOBS Act. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

***Provisions in our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and amended and restated by-laws that will become effective upon the closing of this offering contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- authorize “blank check” preferred stock, which could be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified board of directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our board of directors pursuant to a resolution adopted by a majority of the total number of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum;
- require a supermajority vote of the holders of our common stock or the majority vote of our board of directors to amend our amended and restated by-laws; and
- require a supermajority vote of the holders of our common stock to amend the classification of our board of directors into three classes and to amend certain other provisions of our certificate of incorporation.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management.

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Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, our amended and restated by-laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

### ***Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.***

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Our existing NOLs may be subject to substantial limitations arising from previous ownership changes, and if we undergo an ownership change in connection with or after this offering, our ability to utilize NOLs could be further limited by Section 382 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. federal taxable income. As described above under “—Risks related to our financial position and need for additional capital,” we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. federal taxable income necessary to utilize our NOLs. A full valuation allowance has been provided for the entire amount of our NOLs.

### ***Our amended and restated certificate of incorporation designates the state or federal courts located in the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation that will become effective upon the closing of this offering provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated by-laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our amended and restated certificate of incorporation described above. This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our amended and restated certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

### ***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

You should not rely on an investment in our common stock to provide dividend income. We do not anticipate that we will pay any cash dividends to holders of our common stock in the foreseeable future. Instead, we plan to

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retain any earnings to maintain and expand our operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase our common stock.

### Cautionary Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements. These statements include all matters that are not related to present facts or current conditions or that are not historical facts, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth. The words “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “will,” “would,” or the negative of these terms or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- the timing of data from our pending Phase 2b trial of AKB-6548, the timing of commencement of our Phase 3 development program of AKB-6548 and the timing of our submission of an NDA for AKB-6548;
- our plans to commercialize AKB-6548, if it is approved;
- our development plans with respect to AKB-6899;
- the timing or likelihood of regulatory filings and approvals, including any required post-marketing testing or any labeling and other restrictions;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the rate and degree of market acceptance and clinical utility of our products;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry;
- our ability to establish collaborations or obtain additional funding;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our expectations related to the use of proceeds from this offering; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the “Risk Factors” section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking

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statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

**Industry and Market Data**

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.



### Use of Proceeds

We estimate that the net proceeds from the sale of \_\_\_\_\_ shares of common stock in this offering will be approximately \$ \_\_\_\_\_ million at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares in full, we estimate that the net proceeds will be approximately \$ \_\_\_\_\_ million after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase or decrease our net proceeds by \$ \_\_\_\_\_ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 1,000,000 shares in the number of shares offered by us would increase or decrease the net proceeds to us by \$ \_\_\_\_\_ million, assuming no change in the assumed initial public offering price of \$ \_\_\_\_\_ per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We intend to use the net proceeds from this offering as follows:

- approximately \$ \_\_\_\_\_ million to continue clinical development of AKB-6548 in patients with anemia secondary to CKD, including the preparation for and initiation of the Phase 3 trials;
- approximately \$ \_\_\_\_\_ million to conduct a Phase 2 clinical trial of AKB-6548 in idiopathic anemia of aging;
- approximately \$ \_\_\_\_\_ million to advance our preclinical candidate, AKB-6899, through Phase 1 development in oncology; and
- the remainder for working capital and other general corporate purposes.

Our expected use of net proceeds from this offering represents our intentions based upon our present plans and business conditions, which could change in the future as our plans and business conditions evolve. The amount and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of preclinical studies, our ongoing clinical studies or clinical studies we may commence in the future, the timing of regulatory submissions and the feedback from regulatory authorities. As a result, our management will have broad discretion over the use of the net proceeds from this offering.

Pending the use of the proceeds from this offering, we intend to invest the net proceeds in short-term, interest-bearing, investment-grade securities, certificates of deposit or government securities.

**Dividend Policy**

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of any then-existing debt instruments and other factors the board of directors deems relevant.

### Capitalization

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2013:

- on an actual basis;
- on a pro forma basis to give effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 6,858,496 shares of common stock upon the closing of this offering and the filing of our amended and restated certificate of incorporation upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to the sale of \_\_\_\_\_ shares of our common stock offered in this offering, assuming an initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information together with our financial statements and related notes appearing elsewhere in this prospectus and the information set forth under the heading “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

	As of December 31, 2013		
	Actual	Pro Forma	Pro Forma, as Adjusted
Cash and cash equivalents	\$ 21,215,228	\$ 21,215,228	\$
Series A redeemable convertible preferred stock, par value \$0.00001 per share; 734,538 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted (Aggregate liquidation preference of \$39,367,094 at December 31, 2013)	\$ 39,367,094	\$ —	\$
Series B redeemable convertible preferred stock, par value \$0.00001 per share; 1,287,525 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted (Aggregate liquidation preference of \$21,031,365 at December 31, 2013)	21,257,044	—	
Series C redeemable convertible preferred stock, par value \$0.00001 per share; 3,428,572 shares authorized, 3,302,885 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted (Aggregate liquidation preference of \$97,202,997 at December 31, 2013)	97,202,997	—	
Stockholders’ deficit:			
Preferred Stock, par value \$0.00001 per share; no shares authorized, issued and outstanding, actual, _____ shares authorized, no shares issued and outstanding pro forma and pro forma as adjusted			
Common stock, par value \$0.00001 per share; 8,400,000 shares authorized, 790,483 shares issued and outstanding, actual; _____ shares authorized, 7,648,979 shares issued and outstanding, pro forma and _____ shares authorized, _____ shares issued and outstanding, pro forma as adjusted	7	76	
Additional paid-in capital	—	94,461,641	
Accumulated deficit	(127,072,064)	(63,706,639)	
Total stockholders’ (deficit) equity	(127,072,057)	30,755,078	
Total capitalization	\$ (105,856,829)	\$ 51,970,306	\$

A \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase or decrease each of cash and cash

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equivalents, additional paid-in capital, total stockholders' deficit (equity) and total capitalization on a pro forma as adjusted basis by approximately \$       million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 1,000,000 shares in the number of shares offered by us would increase or decrease each of cash and cash equivalents, additional paid-in capital, total stockholders' deficit (equity) and total capitalization on a pro forma as adjusted basis by approximately \$       million, assuming no change in the assumed initial public offering price of \$       per share and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The actual, pro forma and pro forma as adjusted information set forth in the table above excludes the following:

- 715,085 shares of our common stock issuable upon the exercise of stock options outstanding as of December 31, 2013 at a weighted-average exercise price of \$1.77 per share;
- 88,633 shares of common stock reserved for issuance pursuant to future equity awards under our Amended and Restated 2008 Equity Incentive Plan; and
- 1,020,000 shares of common stock reserved for future issuance under our 2014 Incentive Plan.

### Dilution

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock in this offering and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

We had a historical net tangible book value of \$(127.1) million, or \$(160.8) per share of common stock, as of December 31, 2013. Our historical net tangible book value represents total tangible assets less total liabilities and redeemable convertible preferred stock. Our historical net tangible book value per share is our historical net tangible book value, divided by the number of shares of our common stock outstanding as of December 31, 2013.

The pro forma net tangible book value of our common stock as of December 31, 2013 was \$30.8 million, or \$4.0 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, divided by the pro forma number of shares of our common stock outstanding after giving effect to the automatic conversion of our outstanding preferred stock into an aggregate of 6,858,496 shares of common stock upon the closing of this offering.

After giving further effect to the sale of \_\_\_\_\_ shares of common stock in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus, our pro forma as adjusted net tangible book value as of December 31, 2013 would have been approximately \$ \_\_\_\_\_ million, or approximately \$ \_\_\_\_\_ per share of common stock. This represents an immediate increase in pro forma net tangible book value of \$ \_\_\_\_\_ per share to our existing stockholders and an immediate dilution of \$ \_\_\_\_\_ per share to investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		\$
Historical net tangible book value per share as of December 31, 2013		\$(160.8)
Increase attributable to the pro forma adjustments described above		
Pro forma net tangible book value per share as of December 31, 2013		4.0
Increase in pro forma net tangible book value per share attributable to new investors		
Pro forma as adjusted net tangible book value per share after this offering		
Dilution per share to new investors		\$

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase or decrease our pro forma as adjusted net tangible book value by approximately \$ \_\_\_\_\_ million, the pro forma as adjusted net tangible book value per share by approximately \$ \_\_\_\_\_ and the dilution to investors purchasing shares in this offering by approximately \$ \_\_\_\_\_ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase or decrease of 1,000,000 shares in the number of shares offered by us would increase or decrease our pro forma as adjusted net tangible book value by approximately \$ \_\_\_\_\_ million, the pro forma as adjusted net tangible book value per share by approximately \$ \_\_\_\_\_ and the dilution to investors purchasing shares in this offering by approximately \$ \_\_\_\_\_ per share, assuming no change in the assumed initial public offering price of \$ \_\_\_\_\_ per share and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their option to purchase additional shares, you will experience further dilution.

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The following table summarizes, on a pro forma as adjusted basis as of December 31, 2013, the number of shares of common stock purchased from us, the total consideration and the average price per share paid by existing stockholders (giving effect to the conversion of all outstanding shares of our preferred stock into 6,858,496 shares of common stock upon the completion of this offering) and by investors participating in this offering, after deducting estimated underwriting discounts and commissions and estimated offering expenses, at an assumed initial public offering price of \$ \_\_\_\_\_ per share, the midpoint of the price range set forth on the cover page of this prospectus. As the table illustrates, new investors purchasing shares in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares purchased		Total consideration		Average price per share
	Number	Percent	Amount	Percent	
Existing stockholders		%	\$	%	\$
New investors		%		%	\$
Total		100%		\$ 100%	

A \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase or decrease the total consideration paid by new investors by \$ \_\_\_\_\_ million and increase or decrease the percentage of total consideration paid by new investors by approximately \_\_\_\_\_%, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase or decrease of 1,000,000 shares in the number of shares offered by us would increase or decrease the total consideration paid by new investors by \$ \_\_\_\_\_ million and increase or decrease the percentage of total consideration paid by new investors by approximately \_\_\_\_\_%, assuming no change in the assumed initial public offering price of \$ \_\_\_\_\_ per share.

If the underwriters exercise their option to purchase additional shares in full, pro forma as adjusted net tangible book value as of December 31, 2013 will increase to \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share, representing an increase to existing stockholders of \$ \_\_\_\_\_ per share, and there will be an immediate dilution of an additional \$ \_\_\_\_\_ per share to new investors.

The number of shares of common stock to be outstanding after this offering is based on the number of shares outstanding as of December 31, 2013 and excludes the following:

- 715,085 shares of common stock issuable upon the exercise of outstanding stock options having a weighted-average exercise price of \$1.77 per share;
- 88,633 shares of common stock reserved for issuance pursuant to future equity awards under our Amended and Restated 2008 Equity Incentive Plan; and
- 1,020,000 shares of common stock reserved for future issuance under our 2014 Incentive Plan.

New investors will experience further dilution if any of our outstanding options are exercised, new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities in the future.

**Selected Financial Data**

The selected statements of operations data for the years ended December 31, 2012 and 2013, the period from February 27, 2007 (inception) to December 31, 2013 and the balance sheet data as of December 31, 2012 and 2013 are derived from our audited financial statements included elsewhere in this prospectus. You should read this data together with our financial statements and related notes included elsewhere in this prospectus and the information under the captions “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our historical results for any prior period are not necessarily indicative of results to be expected in any future period, and our interim period results are not necessarily indicative of results to be expected for a full year or any other interim period.

	<u>Year Ended December 31,</u>		<u>Period from</u>
	<u>2012</u>	<u>2013</u>	<u>February 27, 2007</u> <u>(inception) to</u> <u>December 31,</u> <u>2013</u>
	(dollars in thousands, except per share data)		
<b>Consolidated statements of operations data:</b>			
Revenue	\$ —	\$ —	\$ —
Expenses:			
Research and development	5,632	10,781	51,748
General and administrative	2,891	5,152	15,269
Total expenses	<u>8,523</u>	<u>15,933</u>	<u>67,017</u>
Loss from operations	(8,523)	(15,933)	(67,017)
Other income, net	327	2,766	3,975
Net loss	<u>\$ (8,196)</u>	<u>\$ (13,167)</u>	<u>\$ (63,042)</u>
Net loss per share applicable to common stockholders—basic and diluted <sup>(1)</sup>	\$ (48.68)	\$ (222.14)	\$ (841.82)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	236,633	310,858	154,875
Pro forma net loss per share applicable to common stockholders—basic and diluted (unaudited) <sup>(1)</sup>		<u>\$ (2.30)</u>	
Pro forma weighted-average number of common shares used in pro forma net loss per share applicable to common stockholders—basic and diluted (unaudited)		<u>5,790,016</u>	

(1) See Note 2 within the notes to our financial statements appearing elsewhere in this prospectus for a description of the method used to calculate basic and diluted net loss per share of common stock. Pro forma basic and diluted net loss per share of common stock is calculated by dividing net loss attributable to common stockholders, excluding the impact of gains (losses) on the extinguishment of preferred stock, accretion of preferred stock and including the impact of compensation expense associated with awards of restricted stock that contain a performance condition wherein vesting is contingent upon our consummation of a Liquidity Event by the pro forma weighted-average number of common shares outstanding.

	<u>December 31,</u>	
	<u>2012</u>	<u>2013</u>
	(in thousands)	
<b>Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 1,641	\$ 21,215
Working capital (deficit)	(2,679)	29,529
Total assets	2,244	34,665
Redeemable convertible preferred stock	56,909	157,827
Deficit accumulated during the development stage	(59,588)	(127,072)
Total stockholders’ deficit	(59,588)	(127,072)

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

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are a biopharmaceutical company focused on the development of novel proprietary therapeutics based on hypoxia inducible factor, or HIF, biology and the commercialization of these products for patients with kidney disease. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body and a potentially novel mechanism of treating anemia. Our lead product candidate, AKB-6548, is being developed as a once-daily oral therapy that has successfully completed a Phase 2a proof of concept study demonstrating that AKB-6548 safely and predictably raised hemoglobin levels in patients with anemia secondary to chronic kidney disease, or CKD, not requiring dialysis.

We are conducting a Phase 2b trial for AKB-6548 in patients with anemia secondary to CKD who are not dependent on dialysis and expect data to be available in the fourth quarter of 2014. We have also initiated a development program for patients dependent on dialysis. If the results of our Phase 2b trial are positive, we would expect to initiate Phase 3 trials for anemia secondary to CKD in 2015, and would anticipate submitting an NDA for AKB-6548 in the United States by 2018 if the Phase 3 data are favorable.

We own worldwide rights to our HIF-based product candidates, including AKB-6548. If approved by regulatory authorities, we plan to commercialize AKB-6548 in the United States ourselves and intend to seek one or more collaborators to commercialize the product candidate in additional markets.

Since our inception in 2007, we have devoted substantially all of our resources to our development efforts relating to AKB-6548, including preparing for and conducting clinical studies of AKB-6548, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the private placement of preferred stock, common stock and convertible notes.

In December 2011, we spun out our programs focused on the treatment of diabetic eye disease and inflammatory bowel disease into Aerpio which has since operated as a stand-alone company. We have administrative services agreements with Aerpio under which we obtain from and provide to Aerpio certain services including consulting services and use of premises.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were \$8.2 million and \$13.2 million for the years ended December 31, 2012 and 2013, respectively. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- continue our Phase 2b trial and prepare for a future Phase 3 development program of AKB-6548 for the treatment of anemia secondary to CKD;



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- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- initiate additional preclinical, clinical or other studies for AKB-6548, AKB-6899 and other product candidates that we may develop or acquire;
- seek to discover and develop additional product candidates;
- acquire or in-license other commercial products, product candidates and technologies;
- make royalty milestone or other payments under any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. We have no manufacturing facilities and all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party CROs to carry out our clinical development activities and we do not yet have a sales organization. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our products.

### **Financial Operations Overview**

#### ***Revenue***

To date, we have not generated any revenues from the sales of products or other means.

Our ability to generate product revenue and become profitable depends upon our ability to successfully develop and commercialize products. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenues from the sale of our products, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

#### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;

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- expenses incurred under agreements with the CROs and investigative sites that will conduct our clinical studies;
- the cost of acquiring, developing and manufacturing clinical study materials;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs associated with preclinical and clinical activities.

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of the current or future clinical studies of our product candidates or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors, including:

- the rate of progress, results and cost of completing our Phase 2b clinical trial of AKB-6548;
- assuming AKB-6548 advances to Phase 3, the scope, size, rate of progress, results and costs of initiating and completing our Phase 3 development program of AKB-6548;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for AKB-6899 and any other product candidates that we may develop or acquire;
- the cost of having our product candidates manufactured for clinical trials;
- difficulties or delays in enrolling patients in our clinical trials;
- unanticipated changes to laws or regulations applicable to our clinical trials; and
- the timing of, and the costs involved in, obtaining regulatory approval for AKB-6548 and any other product candidates, if clinical trials are successful.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, EMA or another regulatory authority were to require us to conduct clinical studies beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical studies, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through December 31, 2013, we have incurred \$51.7 million in research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development of our AKB-6548 product candidate. Our current and planned research and development activities include the following:

- We plan to complete a Phase 2b clinical study during 2014 to examine the safety and efficacy of AKB-6548 in patients with anemia secondary to CKD.
- We plan to initiate a Phase 3 development program for AKB-6548 in 2015 for anemia secondary to CKD.
- We have begun an efficacy study for AKB-6548 in dialysis patients with anemia, the second indication we will pursue.

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- We intend to conduct a Phase 2 clinical trial of AKB-6548 in IAA.
- We intend to file an Investigational New Drug, or IND, and begin Phase 1 trials for AKB-6899 and explore its use in oncology and ophthalmology.

Our direct research and development expenses consist principally of external costs, such as startup fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials.

We currently have one program to which our research and development costs are attributable. Historically, we have not accumulated and tracked our research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources, and many of our costs were directed to broadly applicable research endeavors. As a result, we cannot state the historical costs incurred for each of our programs on a program-by-program basis.

### **General and Administrative Expenses**

We obtain from and provide to Aerpio services under the terms of administrative services agreements between the two companies. See “Certain Relationships and Related Party Transactions.” General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance and human resource functions. Other general and administrative expenses include facility-related costs and professional fees for directors, accounting and legal services, recruiting fees and expenses associated with obtaining and maintaining patents.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission requirements, director and officer insurance premiums, and investor relations costs associated with being a public company. Additionally, if and when we believe a regulatory approval of the first product candidate appears likely, we anticipate an increase in payroll and related expenses as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidates.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our management’s discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this prospectus, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

### ***Accrued Research and Development Expenses***

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time. We confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include expenses for:

- CROs in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. The scope of services under these contracts can be modified and the agreements can be cancelled by either party upon written notice. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed we may report amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates and the amount actually incurred.

### ***Stock-Based Compensation***

#### *Stock-Based Awards*

We issue stock-based awards to employees and non-employees, generally in the form of stock options, restricted stock and shares of common stock. We account for our stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock and modifications to existing stock awards to be recognized in the statements of operations and comprehensive loss based on their fair values. We account for stock-based awards to non-employees in accordance with FASB ASC Topic 505-50, *Equity-Based-Payments to Non-Employees*, or ASC 505-50, which requires the fair value of the award to be re-measured at fair value until a performance commitment is reached or counterparty performance is complete. Described below is the methodology we have utilized in measuring stock-based compensation expense. Following the consummation of this offering, stock option, common stock and restricted stock values will be determined based on the quoted market price of our common stock.

We estimate the fair value of our stock-based awards of options to purchase shares of common stock to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term

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assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to our company, including stage of product development and life science industry focus. We are a development stage company in a very early stage of product development with no revenues and the representative group of companies has certain similar characteristics. We believe the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of our company. We performed a sensitivity analysis to determine the impact a 30% increase or decrease in the volatility rate would have on the fair value of each stock-based award, and determined that such a rate change would be immaterial to the calculation of stock-based compensation. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. For options granted to non-employees, we utilize the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock, similar to our peer group. We estimate grant date fair value of restricted stock awards with corresponding promissory notes using the Black-Scholes option pricing model. The grant date fair value of restricted stock award grants without a promissory note and awards of common stock is based on the estimated value of our common stock at the date of grant.

Our stock-based awards are subject to either service or performance-based vesting conditions. Compensation expense related to awards to employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with service-based vesting conditions is recognized on a straight-line basis based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with performance-based vesting conditions is recognized based on the then-current fair value at each financial reporting date prior to the measurement date over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

In June 2011, certain of our employees purchased shares of our restricted stock in exchange for promissory notes. Although these notes are 50% recourse to the employees, we have accounted for the promissory notes as nonrecourse in their entirety since the promissory notes are not aligned with a corresponding percentage of the underlying shares. Accordingly, we have accounted for the combination of the promissory note and restricted stock as a grant of an option, as the substance is similar to the grant of an option. The exercise price of this stock option is the principal and interest due on the promissory note. The fair value of the stock option is recognized over the requisite service period (not the term of the promissory note) through a charge to compensation cost. The maturity date of the promissory notes reflects the legal term of the stock option for purposes of valuing the award. These awards are referred to as promissory note options in the tables below.

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We have computed the fair value of employee and non-employee stock options at date of grant using the following weighted-average assumptions:

	Year Ended December 31,	
	2012	2013
Expected volatility	73.00%	79.00%
Expected term (in years)—employee options	6.25	6.25
Expected term (in years)—non employee options	10	10
Expected term (in years)—promissory note options	5	5
Risk-free interest rate	0.95%	1.71%
Expected dividend yield	0.00%	0.00%
Expected dividend yield—promissory note options	6.00%	3.00%

The following table presents the grant dates, number of underlying shares and related exercise prices or purchase prices of stock options granted and restricted stock awards issued between January 1, 2011 and December 31, 2013, along with the fair value per share utilized to calculate stock-based compensation expense:

Year of grant	Type of award	Number of shares	Exercise price (options) or purchase price (promissory note options) per share	Retrospective common stock fair value per share as of grant date
2011	Option	24,330	1.50	1.90
2011	Restricted Stock Award	145,404 <sup>(1)</sup>	N/A	1.90
2011	Common Stock Awards	22,286	N/A	1.90
2012	Option	40,451	1.50	1.00
2012	Restricted Stock Award	30,047	N/A	1.00
2013	Option	526,347	0.82-6.60	6.60-12.99
2013	Restricted Stock Award	30,763	N/A	1.56
2013	Common Stock Awards	100,981	N/A	6.60-12.99

(1) Represents promissory note options, as described above.

Stock-based compensation totaled approximately \$0.1 million for the year ended December 31, 2012 and approximately \$1.6 million for the year ended December 31, 2013. As of December 31, 2013, we had approximately \$3.4 million of total unrecognized compensation expense related to stock options and approximately \$0.1 million of total unrecognized compensation expense related to restricted stock grants with only service based vesting conditions, which are expected to be recognized over a weighted-average remaining vesting period of approximately 2.3 years and 1.8 years, respectively. As of December 31, 2013, we also had approximately \$3.9 million of total unrecognized compensation expense related to restricted stock grants with performance conditions which will be recognized commencing upon the occurrence of a Liquidity Event.

We expect the impact of our stock-based compensation expense for stock options and restricted stock granted to employees and non-employees to grow in future periods due to the potential increases in the fair value of our common stock and the increase in the number of grants as a result of an increase in headcount.

### Fair Value of Stock Options

We have historically granted stock options at exercise prices not less than the fair value of our common stock as of the actual date of grant. As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined contemporaneously by our board of directors based on valuation estimates provided by third party valuations prepared for purposes of income tax reporting under Section 409A of the Internal Revenue Code.

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In October 2013, in consideration of the improving market for initial public offerings by biopharmaceutical companies, our board of directors directed us to begin preparation of a registration statement for an initial public offering. We selected underwriters and held an organizational meeting on November 18, 2013. We believe these events increased the probability of an early initial public offering.

As a result, in connection with the preparation of our financial statements for the years ended December 31, 2012 and 2013, and the period from February 27, 2007 (date of inception) to December 31, 2013, we reexamined the valuation of our common stock. In connection with that reexamination, we prepared retrospective appraisals of the fair value of our common stock for financial reporting purposes as of December 31, 2012 March 31, 2013 and September 30, 2013. Prior to 2013, our contemporaneous valuations were prepared to comply with Section 409A of the Internal Revenue Code. As a result, the contemporaneous valuations were not performed under the fair value framework as set forth under ASC 820 and did not take into account the guidance provided in the American Institute of Certified Public Accountants' (AICPA) Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Accordingly, the contemporaneous valuations had limited value for purposes of financial reporting under U.S. GAAP. Therefore, in connection with the preparation of our financial statements, we re-assessed the fair value of our common stock for financial reporting purposes by having retrospective valuations performed in accordance with the fair value framework under ASC 820 and the AICPA Technical Practice Aid. We believe that the valuation methodologies used in the retrospective valuations are reasonable and consistent with the AICPA Practice Aid. The fair values of our common stock shown in the table above reflect these retrospective valuations.

The table below summarizes the common stock values determined in our contemporaneous and retrospective valuations:

<u>Date</u>	<u>Contemporaneous</u>	<u>Retrospective</u>
December 31, 2012	\$ 1.50	\$ 1.00
March 31, 2013	n/a	\$ 1.56

### *December 31, 2012 Retrospective Valuation*

For the retrospective valuation at December 31, 2012, we used the guideline public company method under the market approach to value our equity. We estimated our equity value based on a multiple of paid-in capital as indicated by a group of guideline public companies. In our selection of guideline public companies, we took into account each candidate's stage of clinical development and the targeted indications for drugs in development. We used the option-pricing method, or OPM, to allocate the value of our equity among our preferred and common stock. We applied a discount for lack of marketability to the value indicated for our common stock. Our estimate of the appropriate discount for lack of marketability took into consideration put option methodologies consistent with the AICPA Practice Aid.

The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the liquidation preference at the time of a liquidity event, such as a strategic sale, merger or IPO. The common stock is modeled as a call option on the underlying equity value at a predetermined exercise price. In the model, the exercise price is based on a comparison with the total equity value rather than, as in the case of a regular call option, a comparison with a per share stock price. Thus, common stock is considered to be a call option with a claim on the enterprise at an exercise price equal to the remaining value immediately after the preferred stock is liquidated. The OPM uses the Black-Scholes option pricing model to price the call options. This model defines the securities' fair values as functions of the fair value of a company's equity as of an appraisal date and uses assumptions such as the anticipated timing of a potential liquidity event and the estimated volatility of the equity securities.

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The following table summarizes the significant assumptions used in the OPM to determine the fair value of our common stock as of December 31, 2012:

### December 31, 2012 retrospective valuation

#### **Key assumptions**

Years to liquidity	1.96
Annual volatility	58%
Risk-free interest rate	0.25%
Discount for lack of marketability (DLOM)	19%

Based on these assumptions, we estimated the fair value of our common stock to be \$1.00 as of December 31, 2012.

#### *March 31, 2013 Retrospective Valuation*

For the retrospective valuation at March 31, 2013, we used the hybrid method to value our common stock. The hybrid method is a hybrid between the probability-weighted expected returns method and the OPM. We considered an IPO scenario, in which our preferred shares convert to common stock, and a second scenario, in which equity value is allocated using the OPM. We used the guideline public company method under the market approach to value our equity. We estimated our equity value based on a multiple of paid-in capital as indicated by a group of guideline public companies. In addition, we estimated the value of our equity securities in association with an IPO. We considered the enterprise values of guideline public companies and the pricing of IPOs completed by clinical stage drug development companies in the year preceding our appraisal date. For each of the IPO companies, we considered the increase, or step-up, in per share value from the preferred financing preceding the IPO to the common stock value in the IPO. We also considered the equity value of each IPO company, not including the proceeds of the IPO.

The following table summarizes the significant assumptions used in the hybrid method to determine the fair value of our common stock as of March 31, 2013:

### March 31, 2013 retrospective valuation

#### **Key assumptions**

	<u>IPO</u>	<u>OPM</u>
Probability weighting	5%	95%
Years to liquidity	1.71	1.71
Weighted-average cost of capital	20%	
Annual volatility		59%
Risk-free interest rate		0.22%
Discount for lack of marketability (DLOM)	18%	18%
Estimated per share present value of non-marketable common stock (before probability weighting)	\$9.75	\$ 1.00

Based on these assumptions, we estimated the fair value of our common stock to be \$1.56 as of March 31, 2013.

The estimated per share fair value of our common stock calculated in our March 31, 2013 retrospective valuation of \$1.56 per share increased from the December 31, 2012 valuation of \$1.00 per share primarily due to the following factors:

- Litigation to protect our intellectual property rights in Europe was decided in our favor.
- We made progress toward completing a Series C preferred stock financing, enhancing our prospects for securing the capital needed for clinical trials prior to an IPO.
- We raised additional capital by issuing Series X preferred shares, and the terms of the Series X shares were revised to the benefit of the common stockholders.



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### *September 30, 2013 Valuation*

For the contemporaneous valuation at September 30, 2013, we used the probability-weighted expected returns method (PWERM). Under PWERM, the values of the various equity securities are estimated based upon an analysis of future values for the enterprise, assuming various future outcomes. Share value is based upon the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available to the enterprise, as well as the rights of each share class.

We considered three scenarios: an IPO, a sale of the Company and a liquidation of the Company's assets. For the IPO scenario, we considered the enterprise values of guideline public companies and the pricing of IPOs completed by clinical stage drug development companies in the year preceding our appraisal date. For each of the IPO companies, we considered the increase, or step-up, in per share value from the preferred financing preceding the IPO to the common stock value in the IPO. We also considered the equity value of each IPO company, not including the proceeds of the IPO. For the sale scenario, we assumed a market participant acquisition premium (MPAP) to the IPO value. Our estimate of the MPAP took into account the premiums observed in eight acquisitions completed in 2013 of publicly-traded clinical stage drug development companies. For the liquidation scenario, we considered a value equal to the amount invested in our Series C preferred stock.

The following table summarizes the significant assumptions used in the PWERM to determine the fair value of our common stock as of September 30, 2013:

	<u>IPO</u>	<u>Sale</u>	<u>Liquidation</u>
Probability	33%	25%	42%
Years to Liquidity	0.48	1.25	1.75
Weighted-average cost of capital	20%	20%	20%
Discount for lack of marketability (DLOM)	12%	20%	NA

Based on these assumptions, we estimated the fair value of our common stock to be \$6.60 as of September 30, 2013.

The estimated per share fair value of our common stock calculated in our September 30, 2013 valuation of \$6.60 per share increased from the March 31, 2013 valuation of \$1.56 per share primarily due to the following factors:

- We completed our Series C preferred stock financing.
- We completed our Phase 2a dose-ranging study of AKB-6548 in patients with stage 3 and 4 CKD.
- Capital market conditions for biotechnology companies improved, as evidenced by an increase in the number of IPOs and their IPO valuations.
- We estimated that the probability of the Company completing an IPO increased.

### *December 31, 2013 Valuation*

For the contemporaneous valuation at December 31, 2013, we used the PWERM method.

We considered three scenarios: an IPO, a sale of the Company and a liquidation of the Company's assets. For the IPO scenario, we considered the enterprise values of guideline public companies and the pricing of IPOs completed by clinical-stage drug development companies in the year preceding our appraisal date. For each of the IPO companies, we considered the increase, or step-up, in per share value from the preferred financing preceding the IPO to the common stock value in the IPO. We also considered the equity value of each IPO company, not including the proceeds of the IPO. For the sale scenario, we assumed a MPAP to the IPO value. Our estimate of the MPAP took into account the premiums observed in nine acquisitions completed in 2013 of publicly-traded clinical-stage drug development companies. For the liquidation scenario, we considered a value equal to the amount invested in our series C preferred stock.

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The following table summarizes the significant assumptions used in the PWERM to determine the fair value of our common stock as of December 31, 2013:

	<u>IPO</u>	<u>Sale</u>	<u>Liquidation</u>
Probability	70%	15%	15%
Years to Liquidity	0.22	1.00	1.50
Weighted-average cost of capital	20%	20%	20%
DLOM	8%	18%	NA

Based on these assumptions, we estimated the fair value of our common stock to be \$12.99 as of December 31, 2013.

The estimated per share fair value of our common stock calculated in our December 31, 2013 valuation of \$12.99 per share increased from the September 30, 2013 valuation of \$6.60 per share primarily due to the increase in the probability of completing an IPO.

There are significant judgments and estimates inherent in the determination of these valuations. These judgments and estimates include assumptions regarding our future performance, including the successful enrollment and completion of our clinical studies as well as the determination of the appropriate valuation methods. If we had made different assumptions, our stock-based compensation expense could have been different. The foregoing valuation methodologies are not the only methodologies available and they will not be used to value our common stock once this offering is complete. We cannot make assurances as to any particular valuation for our common stock. Accordingly, we caution you not to place undue reliance on the foregoing valuation methodologies as an indicator of future stock prices.

The Company has recognized the following compensation cost related to employee and non-employee based stock option, restricted stock and common stock activity:

<u>Year Ended</u>	<u>Research and Development</u>	<u>General and Administrative</u>	<u>Total</u>
2013	\$ 110,686	\$ 1,453,073	\$1,563,759
2012	52,768	69,573	122,341
2011	175,418	132,011	307,429

### ***Emerging Growth Company Status***

The JOBS Act, permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We are choosing to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

### ***Recently Adopted Accounting Pronouncements***

In February 2013, the FASB issued guidance to provide information about the amounts reclassified out of accumulated other comprehensive income, or AOCI, by component. An entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. On January 1, 2013, we adopted this standard, which had no impact on our financial position or results of operations.

[Table of Contents](#)**Results of Operations****Comparison of the Years Ended December 31, 2012 and 2013**

	Year ended December 31,		Increase (Decrease)
	2012	2013	
Revenue	\$ —	\$ —	\$ —
Expenses:		(in thousands)	
Research and development	5,632	10,781	5,149
General and administrative	2,891	5,152	2,261
Total expenses	8,523	15,933	7,410
Loss from operations	(8,523)	(15,933)	7,410
Other income, net	327	2,766	2,439
Net loss	\$ (8,196)	\$ (13,167)	\$ 4,971

*Research and Development Expenses.* Research and development expenses were \$10.8 million for the year ended December 31, 2013, compared to \$5.6 million for the year ended December 31, 2012, an increase of \$5.1 million. The increase was primarily due to an increase in AKB-6548 clinical trial costs of approximately \$2.5 million due to the initiation of our Phase 2b study in July 2013 and its continued enrollment, an increase of approximately \$1.3 million in drug substance and drug manufacturing costs and increased patent costs of approximately \$1.3 million.

*General and Administrative Expenses.* General and administrative expenses were \$5.2 million for the year ended December 31, 2013, compared to \$2.9 million for the year ended December 31, 2012. The increase of \$2.3 million was primarily due to an increase in stock-based compensation expense of \$1.4 million and increased professional fees of \$0.5 million indirectly related to the initial public offering. The remaining increase was due to offsetting increases and decreases in all general and administrative costs.

*Other Income, Net.* Other income, net, was \$2.8 million for the year ended December 31, 2013, compared to \$0.3 million for the year ended December 31, 2012, an increase of approximately \$2.4 million. Other income, net for the year ended December 31, 2013 included \$1.0 million in reimbursements from Aerpio for employee-related costs of the Company and a \$2.4 million gain on the extinguishment of debt, partially offset by net interest expense of \$0.7 million. Other income, net for the year ended December 31, 2012 included \$2.0 million in reimbursements from Aerpio for employee-related costs of the Company, partially offset by net interest expense of \$1.6 million. The decrease in reimbursements from Aerpio for employee-related costs of the Company is principally the result of reduced time spent by our employees on Aerpio related activities. Under the terms of the administrative services agreements entered into upon disposition of Aerpio by the Company in 2011, the Company and Aerpio obtain from and provide to each other certain services.

**Liquidity and Capital Resources**

We have incurred losses and cumulative negative cash flows from operations since our inception in February 2007, and as of December 31, 2013, we had an accumulated deficit of \$127.1 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

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We have funded our operations principally from the sale of common stock, preferred stock and convertible notes. As of December 31, 2013, we had cash and cash equivalents of approximately \$21.2 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Investments, consisting principally of corporate and government debt securities and stated at fair value, are also available as a source of liquidity.

### **Cash Flows**

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Year ended December 31,	
	2012	2013
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (7,211)	\$ (11,332)
Investing activities	1,366	(11,425)
Financing activities	2,475	42,331
Net (decrease) increase in cash and cash equivalents	\$ (3,370)	\$ 19,574

*Operating Activities.* The net cash used in operating activities was \$11.3 million for the year ended December 31, 2013, and consisted primarily of a net loss of \$13.2 million adjusted for non-cash items including gain on extinguishment of debt of \$2.4 million, stock-based compensation expense of \$1.6 million, amortization of debt discount of \$0.8 million and a net increase in operating assets and liabilities of \$1.9 million. The significant items in the change in operating assets and liabilities include increases in accounts payable and accrued expenses of \$2.3 million, offset by a decrease in prepaid expenses, other current assets and other assets of \$0.3 million. The increase in accounts payable and accrued expenses is driven by professional fees incurred in connection with our planned initial public offering.

The net cash used in operating activities was \$7.2 million for the year ended December 31, 2012, and consisted primarily of a net loss of \$8.2 million adjusted for non-cash items including amortization of debt issue costs and debt discount of \$1.7 million and stock-based compensation expense of \$0.1 million and a net decrease in operating assets and liabilities of \$0.8 million. The significant items in the change in operating assets and liabilities include a decrease in accounts payable and accrued expenses of \$1.0 million, offset by an increase in prepaid expenses and current assets of \$0.2 million.

*Investing Activities.* Net cash provided by (used in) investing activities consisted of purchases of fixed assets, purchases of marketable securities, and proceeds from the maturity and sale of marketable securities. Net cash used in investing activities for the year ended December 31, 2013 was \$11.4 million and was comprised primarily of purchases of investments of \$13.4 million, offset by proceeds from maturities of investments of \$2.0 million. Net cash provided by investing activities for the year ended December 31, 2012 was \$1.4 million and consisted completely of proceeds from sales of investments.

*Financing Activities.* Net cash provided by financing activities for the year ended December 31, 2013 was \$42.3 million and consisted primarily of \$41.2 million of proceeds from the issuance of preferred stock, \$2.5 million of proceeds from the issuance of 25,000 shares of Series X preferred stock, partially offset by stock issuance costs of \$1.2 million and initial public offering related costs of \$0.2 million. Net cash provided by financing activities for the year ended December 31, 2012 is the result of the sale of 25,000 shares of our Series X preferred stock for net proceeds of \$2.5 million.

**Operating Capital Requirements**

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to all of the risks incident in the development and commercialization of novel therapeutics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. Upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We believe that the net proceeds from this offering and our existing cash and cash equivalents will be sufficient to fund our projected operating requirements into . However, we may require additional capital for the further development of our existing product candidates and may also need to raise additional funds sooner to pursue other development activities related to additional product candidates.

If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity or debt offerings. Additional capital may not be available on reasonable terms, if at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders, increased fixed payment obligations and these securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to:

- the rate of progress, results and cost of completing our Phase 2b clinical trial of AKB-6548 and our operating costs incurred as we conduct these trials and through our end of Phase 2 meeting with the FDA, and equivalent meetings with the EMA and other regulatory authorities;
- assuming positive results from our current Phase 2b trial, the scope, size, rate of progress, results and costs of initiating and completing our Phase 3 development program of AKB-6548;
- assuming favorable clinical results, the cost, timing and outcome of our efforts to obtain marketing approval for AKB-6548 in the United States and in other jurisdictions, including to fund the preparation and filing of regulatory submissions for AKB-6548 with the FDA, the EMA and other regulatory authorities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for AKB-6899 and any other product candidates that we may develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for AKB-6899 if clinical trials are successful and the outcome of regulatory review of AKB-6899;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;

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- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the cost of having our product candidates manufactured for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the need to implement additional infrastructure and internal systems; and
- the extent to which we acquire or in-license other products or technologies.

If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

### Contractual Obligations and Commitments

In December 2013, we entered into a three-year lease for 6,837 square feet of office space in Cambridge, Massachusetts. The lease has monthly lease payments of approximately \$31,000 for the first twelve months, with annual rent escalation thereafter, and provides a rent abatement of approximately \$31,000 for the first full calendar month of the lease term. The lease term commences and rental payments begin in January 2014. We will record a deferred lease obligation in 2014 which will represent the cumulative difference between actual facility lease payments and lease expense recognized ratably over the lease period. We did not have rent expense associated with this lease in 2013.

We lease office equipment under a three year capital lease with payments commencing in 2014.

At December 31, 2013, our future minimum payments required under these leases are as follows:

	Payments due by period				More than 5 years
	Total	Less than 1 year	1-3 years	3-5 years	
Capital Lease Obligations	\$ 12,600	\$ 3,850	\$ 8,750	\$ —	\$ —
Operating Lease Obligations	1,117,280	344,699	772,581	—	—
Total	<u>\$1,129,880</u>	<u>\$348,549</u>	<u>\$781,331</u>	<u>\$ —</u>	<u>\$ —</u>

We contract with various organizations to conduct research and development activities with remaining contract costs to us of \$4.5 million at December 31, 2013. The scope of services under the research and development contracts can be modified and the contracts cancelled by either party upon written notice.

### Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

**Quantitative and Qualitative Disclosures About Market Risks**

We are exposed to market risk related to changes in interest rates. As of December 31, 2012 and 2013, we had cash and cash equivalents and investments of \$1.6 million and \$32.6 million, respectively, primarily money market mutual funds consisting of U.S. government debt securities, certificates of deposit and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our investments are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

## Business

### Overview

We are a biopharmaceutical company focused on the development of novel proprietary therapeutics based on HIF biology and the commercialization of these products for patients with kidney disease. HIF is the primary regulator of the production of RBCs in the body and a potentially novel mechanism of treating anemia. Our lead product candidate, AKB-6548, is being developed as a once-daily oral therapy that has successfully completed a Phase 2a proof of concept study demonstrating that AKB-6548 safely and predictably raised hemoglobin levels in patients with anemia secondary to CKD not requiring dialysis.

We are conducting a Phase 2b trial for AKB-6548 in patients with anemia secondary to CKD who are not dependent on dialysis and expect data to be available in the fourth quarter of 2014. We have also initiated a development program for patients dependent on dialysis. If the results of our Phase 2b trial are positive, we would expect to initiate Phase 3 trials for anemia secondary to CKD in 2015, and would anticipate submitting an NDA for AKB-6548 in the United States by 2018 if the Phase 3 data are favorable.

We own worldwide rights to our HIF-based product candidates, including AKB-6548. If approved by regulatory authorities, we plan to commercialize AKB-6548 in the United States ourselves and intend to seek one or more collaborators to commercialize the product candidate in additional markets.

Anemia is a serious medical condition in which blood is deficient in RBCs and hemoglobin, both of which are critical in delivering oxygen to tissue. Anemia generally exists when hemoglobin, a protein in RBCs that carries oxygen, is less than 13 g/dL in men or 12 g/dL in women. Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases, and death. Anemia is common in patients with CKD, cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly.

More than 30 million people in the United States have CKD, with estimates that over 1.8 million of these patients suffer from anemia. Anemia from these indications is currently treated by injectable recombinant protein erythropoiesis stimulating agents, or rESAs—including Epogen, Aranesp, and Procrit—with iron supplementation or an RBC transfusion. Based on the reported revenues of companies that market and sell rESAs, we estimate that global sales of injectable rESAs were \$6.3 billion in 2012, the vast majority of which were for renal indications.

rESAs are designed to stimulate production of RBCs by binding directly to and saturating EPO receptors. While injectable rESAs and transfusions may be effective in raising hemoglobin levels, they carry significant potential side effects and also need to be delivered subcutaneously or intravenously. In particular, injectable rESAs may lead to thrombosis, stroke, myocardial infarction and death, and these risks are described in black box warnings on the prescribing information of all products marketed in this class. These safety concerns, which became evident starting in 2006, have led to a significant reduction in the use of injectable rESAs. Today anemia is either not treated or inadequately treated in the majority of CKD patients, and we believe that a safe, effective, oral therapeutic option will take significant market share and meaningfully grow the market in patients not requiring dialysis.

AKB-6548 works by a differentiated mechanism of action that we believe has the potential to be safer than that of injectable rESAs. This novel mechanism of action is referred to as HIF-PH inhibition. Instead of binding directly to the EPO receptors on cells in the bone marrow, AKB-6548 leads to activation of critical pathways for hemoglobin and RBC production. This approach mimics the physiological adjustment made by the body when exposed to reduced oxygen levels at higher altitudes.

To date, AKB-6548 has been studied in eight clinical trials across four separate patient populations: healthy volunteers and patients with CKD stages 3, 4 and 5 (non-dialysis). Our largest study was a Phase 2a trial in 91



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patients with anemia secondary to CKD, which showed significantly increased hemoglobin levels among subjects taking AKB-6548 compared to baseline in a dose-dependent manner across all treatment arms ( $p < 0.0001$ ). No drug-related serious adverse events were reported, and dosing was well-tolerated. In addition, AKB-6548 was also shown to stabilize the iron supply to the bone marrow while improving hemoglobin production.

Our ongoing Phase 2b trial explores a dosing approach for AKB-6548 to enable subjects with anemia secondary to CKD to appropriately and safely raise hemoglobin levels. As of February 28, 2014, we had enrolled over 80% of our targeted 200 patients in this study at investigational sites in the United States, with data expected in the fourth quarter of 2014. With positive data, we plan to progress to Phase 3 global registration studies for AKB-6548 in patients with anemia secondary to CKD. We anticipate the design of the Phase 3 studies will mirror the Phase 2b study, except that they will be longer and larger in size, positioning us to file for approval in the United States by 2018.

Given the burdens of the current standard of care and costs associated with administering an injectable rESA, we believe AKB-6548 is a promising alternative for the overall cost-effective treatment of anemia. We intend to commercialize AKB-6548 ourselves in the United States for the treatment of anemia in patients with CKD. These patients are primarily treated by approximately 7,000 nephrologists, and we believe we can reach most of this market with a specialty sales force of approximately 125 people. We intend to seek one or more commercial collaborators for the development and commercialization of AKB-6548 outside of the United States. We may also explore opportunities to expand AKB-6548 into additional markets not adequately addressed by injectable rESAs because of safety or dosing delivery issues, including IAA and anemia of congestive heart failure.

We are led by a team of experienced biopharmaceutical executives with a background in developing and commercializing drugs for the treatment of renal and metabolic disorders. John P. Butler, our CEO, was former President of Genzyme Corp.'s renal division which grew to over \$1 billion in annual revenue under his leadership, and is current Chairman of the Board of the American Kidney Fund, the leading patient advocacy organization for kidney disease patients. Earlier in his career, Mr. Butler held sales and marketing positions at Amgen, working on the early commercial launch of injectable rESAs in the renal anemia market. Our executive team also includes Robert Shalwitz, M.D., CMO and co-founder of Akebia. Dr. Shalwitz is an academic pediatric endocrinologist and has extensive industry experience developing novel pharmaceuticals at Abbott Laboratories and Reliant Pharmaceuticals. He has developed extensive knowledge of HIF biology over his career, particularly over the past seven years in leading development at Akebia.

### **Our Strategy**

Our strategy is to develop novel therapeutics for patients based on HIF biology and to commercialize products for patients with kidney disease, beginning with AKB-6548 for patients with anemia secondary to CKD. The key elements of our strategy are to:

- **Complete the development of AKB-6548 for anemia secondary to CKD.** We plan to complete the Phase 2b trial that is currently enrolling in the United States. We intend to initiate a Phase 3 development program in 2015 following our end of Phase 2 meeting with the FDA.
- **Obtain regulatory approval of AKB-6548 for anemia secondary to CKD in the United States, Europe and other markets.** We plan to complete an end of Phase 2 meeting with the FDA and seek scientific advice from the EMA to define the Phase 3 development program necessary to secure regulatory approval to market AKB-6548. We would expect to initiate Phase 3 trials for anemia secondary to CKD in 2015, and would anticipate submitting an NDA for AKB-6548 in the United States by 2018 if the Phase 3 data are favorable.

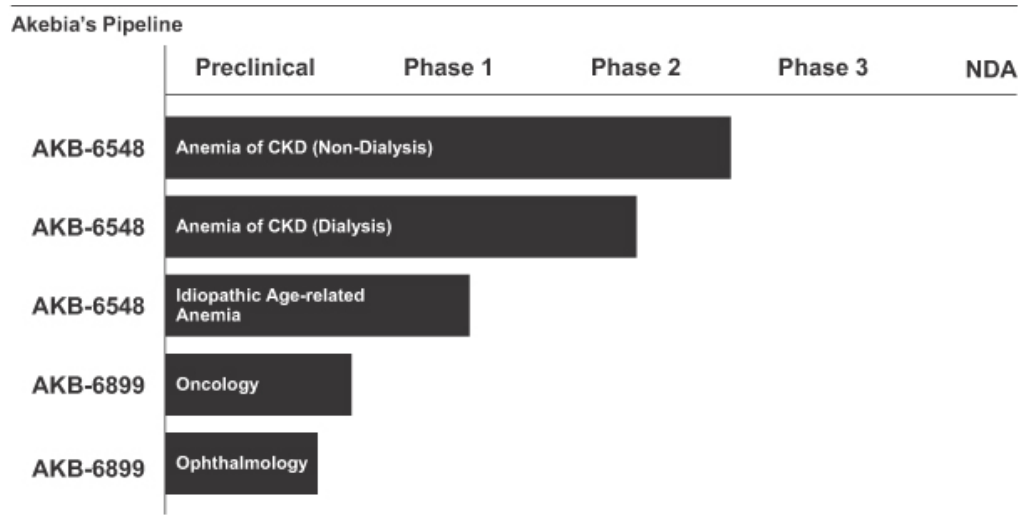
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- **Commercialize AKB-6548 in the United States and other territories.** We will establish a specialty sales and marketing organization to commercialize AKB-6548 in the United States. Outside of the United States, we intend to seek one or more commercial collaborators.
- **Continue to develop AKB-6548 for further indications.** We plan to initiate, in the first half of 2014, a Phase 2 study for AKB-6548 in dialysis patients with anemia, the second indication we intend to pursue. Additionally, we plan to evaluate the product candidate in IAA and other indications.
- **Advance our earlier stage pipeline asset.** We plan to advance AKB-6899, a second HIF-PH inhibitor product candidate, which we believe, based on preclinical testing, has the ability to increase EPO levels while reducing vascular endothelial growth factor, or VEGF, levels. We intend to file an IND application and begin Phase 1 trials to determine its potential use in oncology and ophthalmology.
- **Acquire or in-license additional nephrology products.** If we are able to successfully launch AKB-6548, we will look to leverage our commercial infrastructure with additional products that would be prescribed by nephrologists.

We may enter into strategic collaborations to fully realize all of the elements of our strategy.

### Our Product Candidates

The following chart depicts our HIF-based product candidates, their indications and their current development. We have not conducted separate Phase 1 trials for anemia secondary to CKD in patients on dialysis or for patients with IAA. However, we expect to rely upon data from completed Phase 1 trials of AKB-6548 for anemia secondary to CKD in patients not on dialysis to initiate Phase 2 clinical trials of AKB-6548 for these indications.



### Anemia Overview

Anemia is a serious medical condition in which blood is deficient in RBCs and hemoglobin, leading to inadequate oxygen delivery to tissues and cells throughout the body. RBCs are normally formed in the bone marrow from precursor or progenitor cells. EPO, a hormonal factor primarily produced in the kidney and liver, binds to and activates the EPO receptor on these precursor cells. The activation of the EPO receptor stimulates these cells to divide, differentiate into RBCs that contain hemoglobin, and mobilize into circulation. Hemoglobin is an iron-containing protein in RBCs that transports oxygen to, and carbon dioxide from, the tissues of the body.

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Anemia generally exists when hemoglobin is less than 13 g/dL in men and 12 g/dL in women. Anemia has a number of potential causes, including nutritional deficiencies, iron deficiency, bone marrow disease, medications, and abnormalities in EPO production or sensitivity. Common causes of anemia due to inadequate EPO production include CKD, age, heart failure, inflammatory diseases, cancer and other critical illnesses.

Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases, and death. This morbidity and mortality risk has been clearly shown in the CKD population, where in patients age 66 and older, anemic patients with mid-stage CKD (Stage 3) have a 149% increase in cardiovascular events and patients with severe CKD (Stage 4 and 5) have a 24% increase in cardiovascular events versus non-anemic patients in the same group, according to a paper published in 2006 in the peer-reviewed journal *Blood*. Similarly, compared to non-anemic patients, anemia increases the mortality rate by 199% in mid-stage CKD, and 59% in severe CKD. Successful treatment of anemia significantly improves patients’ quality of life, especially with respect to vitality, fatigue and physical function. In addition, patients whose anemia has been successfully treated have demonstrated lower mortality rates, less frequent hospitalization, and decreases in cardiovascular morbidity.

**Chronic Kidney Disease**

CKD, a common cause of anemia, is a condition in which the kidneys are progressively damaged to the point that they cannot properly filter the blood circulating in the body. This damage can cause waste products to build up in the subject’s blood and can lead to other health problems, including cardiovascular disease, anemia, and bone disease. CKD patients are classified by the degree of their loss of kidney function as measured by the glomerular filtration rate, or GFR, and albuminuria, the protein levels in urine. As seen in the table below, CKD affects more than 30 million people in the United States. As shown in the table below, the prevalence of anemia is associated with the severity of CKD in this population.

**Anemia Prevalence Increases by CKD Stage**

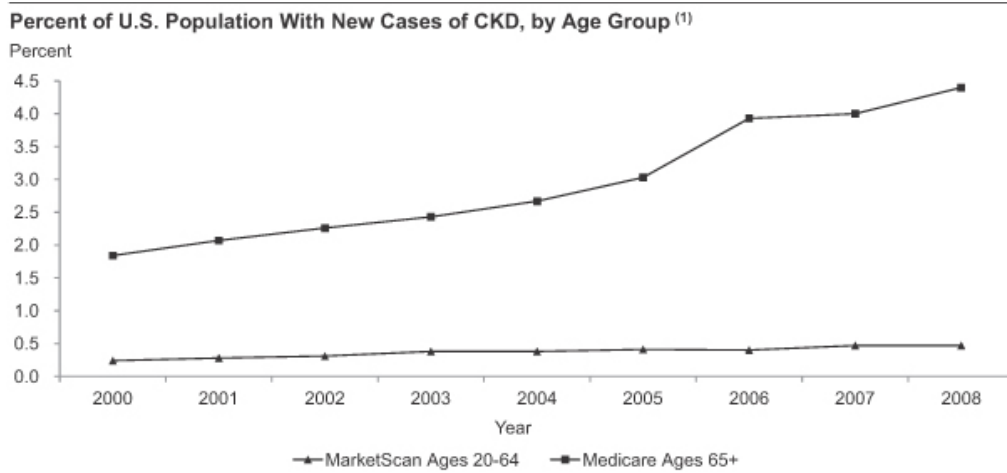
Stage	Prevalence – (diagnosed / undiagnosed)	Kidney Function	Estimated Anemia Prevalence (with CKD diagnosis)	Estimated U.S. Anemia Patients (with CKD diagnosis)
1	~4M	Persistent albuminuria with GFR higher than 90 mL/min/1.73 m2	<1%	~18,000
2	~8M	Persistent albuminuria with GFR of 60 to 89 mL/min/1.73 m2 Mild (GFR: 60 – 89)	1 – 2%	~65,000
3	~17M	GFR of 30 to 59 mL/min/1.73 m2 Moderate (GFR: 30 – 59)	6 - 8%	Up to ~605,000
4	~1M	GFR of 15 to 29 mL/min/1.73 m2 Severe (GFR: 15 – 29)	50% to 60%	Up to ~500,000
5	~670,000	Failure (GFR: <15) Includes Dialysis, No Dialysis & Transplants	85%-100%	~650,000

**Sources:**  
 Stages 1-4: JAMA 2007 Coresh et al (Prevalence of CKD in the US), NHANES 1988-94 and 1999-2004.  
 Stage 5: USRDS 2013 report (ESRD).

There are many causes of CKD, the most common of which are diabetes and hypertension. The prevalence and incidence of CKD is increasing in all segments of the U.S. population, particularly in patients over 65, as shown below. Risk factors for the development of CKD include underlying disease (hypertension, diabetes and cardiovascular disease), lifestyle factors (tobacco use and inactivity), family history, aging, and prenatal factors

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(maternal diabetes mellitus, low birth weight and small-for-gestational-age status). Beyond the United States, according to a *Lancet* article from May 2013, projected worldwide population changes suggest that the potential number of cases of kidney disease, specifically end-stage, will increase disproportionately in developing countries, such as China and India, where the numbers of elderly people are expanding. This effect will be enhanced further if the trends of increasing hypertension and diabetes prevalence persist, competing causes of death—such as stroke and cardiovascular diseases—are reduced, and access to treatment improves.



(1) MarketScan represents data from employer group health plans.

Source:  
<http://kidney.niddk.nih.gov/kudis/eases/pubs/kustats/#3>

The prevalence and severity of anemia in CKD increases as renal function deteriorates. Three variables which may combine to accentuate and accelerate anemia as CKD progresses include:

- Peritubular fibroblasts, a type of cell in the kidney, are designed to sense the amount of oxygen carried by the blood. These cells secrete EPO to adjust the production of RBCs and maintain circulating oxygen levels at normal physiologic levels. As kidney disease progresses, the number of peritubular fibroblasts is reduced and EPO secretion is significantly decreased. This decline in EPO leads to a reduction in RBC production.
- CKD leads to a shorter average life span for RBCs (70 days) as compared to healthy individuals (90 to 120 days), requiring increased RBC production to keep RBC levels consistent with those of a healthy individual.
- The availability of iron to the bone marrow is impaired. Iron is a required component in the formation of hemoglobin, and is essential in the transport of both oxygen and carbon dioxide.

As CKD progresses, the combined effect of decreased RBC production from lower EPO signaling, increased rate of RBC destruction, and reduced iron availability to the bone marrow results in the increased prevalence and severity of anemia.

### Current Treatments Leave a Substantial Unmet Need

Injectable rESAs, including epoetin alfa, epoetin beta, and darbepoetin alfa, are currently the standard of care for treating anemia in patients with CKD and must be administered intravenously or subcutaneously with iron supplements. Based on the reported revenues of companies that market and sell rESAs, we estimate that global

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sales of injectable rESAs were \$6.3 billion in 2012, as compared to an estimated \$12 billion in 2006. Of these 2012 revenues, an estimated \$3.4 billion were generated in the United States, the vast majority of which were for renal indications. In 2006, data on the risks of rESA use among these patients started to become available, forcing physicians to balance serious safety concerns against the efficacy of rESAs. The safety concerns with injectable rESA use include increased risk of cardiovascular disease as well as a potentially increased rate of tumor progression in patients with cancer. We believe that the decline in market revenue since 2007 is a direct result of these increased safety concerns, as well as reimbursement pressures, and that an opportunity exists for a safer, well-tolerated alternative to replace injectable rESAs as the standard of care for anemia secondary to CKD.

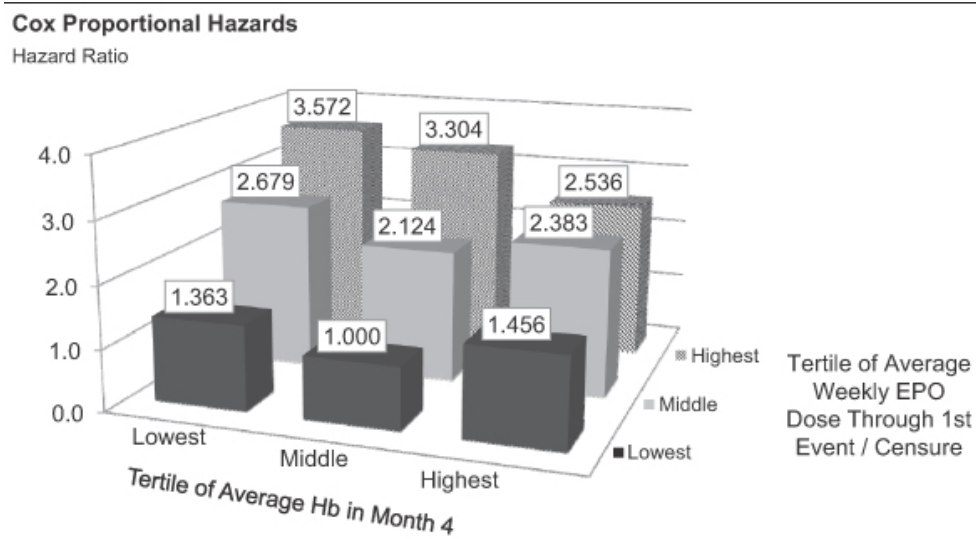
As a result of the safety concerns related to rESA use, patients have been forced to live with lower hemoglobin levels, higher rates of transfusions, and more intravenous iron, or IV iron, use. The percentage of dialysis patients in the United States receiving IV iron has increased from 50% in 1999 to 71% during in 2011, which is consistent with the general trend of increasing IV iron. Among U.S. patients receiving IV iron, the mean monthly dose has also increased by 21%. Despite the increased use of IV iron and rate of transfusions, patients are still subject to safety risks related to these alternative treatments to injectable rESAs. The risks of transfusions include the development of antibodies to foreign antigens, transmission of blood-borne pathogens, impairment of venous access in CKD patients (not on dialysis) and iron overload with chronic transfusion. The risks of IV iron include hypersensitivity reactions, such as fatal anaphylactic-type reactions.

Currently, there is no scientific consensus regarding the adverse cardiovascular outcomes associated with the use of injectable rESAs to normalize hemoglobin levels. The results of the four major randomized, controlled clinical trials on the treatment of anemia secondary to CKD with rESAs and adjunctive iron supplementation (Normal Hematocrit Trial/NHCT; CREATE, CHOIR and TREAT) all showed an increased risk of adverse cardiovascular outcomes. These results were surprising at the time and contradicted the extensive body of data from observational studies that showed reduced mortality and improved health outcomes to be associated with higher hemoglobin levels.

A number of critical post-hoc analyses of the randomized controlled trials data have shifted attention to the potential of dose-related toxicity of injectable rESAs in CKD patients as a contributing factor to the reported adverse cardiovascular outcomes, instead of the role of normalized hemoglobin levels. The strongest correlation of adverse outcomes in the post-hoc analyses has been to the level of the injectable rESA dose, not the hemoglobin level achieved. All of the studies analyzed to date demonstrate that both non-dialysis and dialysis-dependent CKD subjects who achieved normal hemoglobin levels with or without minimal doses of injectable rESAs or supplemental iron had better clinical outcomes than subjects assigned to higher hemoglobin targets who failed to reach the assigned level with increasing doses of injectable rESAs and iron. In addition, CKD patients who are able to achieve and maintain normal hemoglobin levels through means other than the use of injectable rESAs (such as hypoxia or iron supplementation) experienced fewer cardiovascular events and reduced morbidity and mortality. Recent studies of injectable rESA use in various preclinical models (including non-human primates) also showed that the frequency of mortality and thrombotic events cannot be explained solely by the achieved higher hemoglobin levels, but is related to the dose, dose frequency, and dose duration of injectable rESAs.

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The graphs below highlight these findings. The first chart explores the relative risk of serious cardiovascular adverse events, including death, hospitalization for heart failure, stroke or myocardial infarction based upon the hemoglobin achieved during the study as well as the weekly injectable rESA dose. The data clearly show that the risk of adverse cardiovascular events was greatest in those patients receiving the highest injectable rESA doses, regardless of the hemoglobin level that was achieved.



**Source:**  
McCullough P.A. · Barnhart H.X. · Inrig J.K. · Reddan D. · Sapp S. · Patel U.D. · Singh A.K. · Szczech L.A. · Califf R.M. Am J Nephrol 2013;37:549-558 (DOI:10.1159/000351175); Permission granted by S. Karger AG, Basel.

The second graph explores the probability of reaching one of several adverse events (death, stroke, heart failure or myocardial infarction) over time for two different groups:

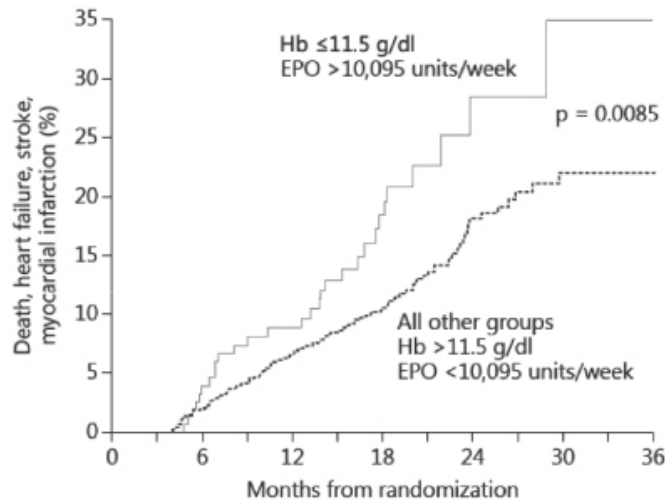
- patients who achieve the target hemoglobin level with a low injectable rESA dose, and
- patients who do not reach the target hemoglobin level, but receive a high injectable rESA dose in an effort to reach the target level.

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This chart is consistent with the previous chart as it shows that patients with high hemoglobin levels on low injectable rESA doses have better outcomes than patients with high injectable rESA doses and low hemoglobin levels. Therefore, high injectable rESA doses, not high hemoglobin levels, appear to be correlated most strongly with adverse outcomes.

### Kaplan-Meier Survival Curves

Death, Heart Failure, Stroke, Myocardial Infarction (%)



**Source:**

McCullough P.A. · Barnhart H.X. · Inrig J.K. · Reddan D. · Sapp S. · Patel U.D. · Singh A.K. · Szczech L.A. · Califf R.M. *Am J Nephrol* 2013;37:549-558 (DOI:10.1159/000351175);  
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The significant safety risks associated with rESAs are outlined in a black-box warning in their prescribing information. This warning arose from numerous events highlighting the safety concerns of injectable rESAs and the responses by the FDA, as highlighted below.

- In 2007, as a result of concerns associated with administering injectable rESAs to target higher hemoglobin levels, the FDA required that revised warnings, including boxed warnings, be added to the labels of marketed injectable rESAs advising physicians to monitor hemoglobin levels and use the lowest dose of injectable rESA, and increase the hemoglobin concentration to the lowest level sufficient to avoid the need for RBC transfusions.
- In November 2007, the FDA found evidence that the use of injectable rESAs to increase hemoglobin to more than 12 g/dL can stimulate progression of some cancers. As a result, injectable rESAs were required to contain black-box labeling for this risk. Following this change in labeling, the use of injectable rESAs in cancer patients has declined significantly.
- In late 2009, Amgen announced the results from the Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy, or TREAT, its large, randomized, double-blind, placebo-controlled Phase 3 study of

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patients with CKD (not requiring dialysis), anemia and type-2 diabetes. In this study, Aranesp was used to treat anemia to a target hemoglobin level of 13 g/dL, which was higher than the 10 g/dL - 12 g/dL range previously approved by the FDA in the label. Study results reportedly failed to show benefit compared to the control group with regard to composite of time to all-cause mortality or cardiovascular morbidity (including heart failure, heart attack, stroke, or hospitalization for myocardial ischemia) and composite of time to all-cause mortality or chronic renal replacement therapy. In addition, higher rates of stroke were reported among patients in the 13 g/dL target group compared to the control group. Finally, among a subgroup of patients with a history of cancer at baseline, a statistically significant increase in deaths from cancer was observed in the Aranesp-treated patients compared to placebo-treated patients.

- In January 2010, FDA officials published an editorial in the New England Journal of Medicine noting that a number of randomized trials, including TREAT, had attempted to show that using injectable rESAs to raise hemoglobin concentrations to higher targets improves clinical outcomes but instead suggested the opposite. Accordingly, the article indicated that more conservative hemoglobin targets (well below 12 g/dL), more frequent hemoglobin monitoring, and more cautious dosing should be evaluated.
- In February 2010, the FDA required that injectable rESAs be prescribed and used under a REMS to ensure the safe use of the drugs. As part of the REMS, a medication guide explaining the risks and benefits of injectable rESAs must be provided to all patients receiving injectable rESAs for all indications, and the FDA imposed reporting and monitoring obligations on the manufacturers to ensure compliance.
- In June 2011, the FDA cited increased risks of cardiovascular events as a basis for more conservative dosing guidelines for use of injectable rESAs in CKD patients and announced related changes to injectable rESA labeling. The FDA removed the prior target hemoglobin range of 10-12 g/dL, and recommended that CKD patients initiate treatment when the hemoglobin level is less than 10 g/dL and reduce or interrupt dosing if the hemoglobin level approaches or exceeds 10 g/dL for non-dialysis patients and 11 g/dL for dialysis patients. The FDA also required Amgen to conduct additional clinical trials to explore dosing strategies to minimize hemoglobin variability, rates of change and excursions.

We believe there is now substantial evidence to suggest that EPO level, not hemoglobin, is the cause of the safety issues in the above trials. The collective preclinical and clinical data support a critical re-thinking on the best approach to treating anemia, the appropriate and safe hemoglobin target, and the right time to initiate treatment for these patients.

### **AKB-6548 as a potential solution**

We are developing our lead product candidate, AKB-6548, to be a best in class HIF-PH inhibitor for the treatment of anemia secondary to CKD. We expect AKB-6548 to offer:

- Predictable, meaningful and sustained improvements in hemoglobin levels;
- Once a day therapy delivered orally;
- A dosing regimen that restores the normal diurnal EPO pattern;
- Robust pharmacodynamics and substantially lower peak EPO levels than with injectable rESAs; and
- Reduced administration of IV or oral iron supplementation to patients treated for anemia secondary to CKD.

### ***Novel Mechanism of Action, Which Mimics the Body's Natural Physiologic Response***

AKB-6548 is designed to work by a mechanism of action that differs from injectable rESAs. This novel mechanism of action is referred to as a HIF-PH inhibitor. Instead of binding directly to and saturating the EPO receptors in the bone marrow for prolonged periods of time, HIF-PH inhibitors act by simulating the body's natural response to anemia. In this way, AKB-6548 achieves a controlled, adaptive stimulation of the erythropoietic system in the body. This activation of the whole system results in both increased RBC production



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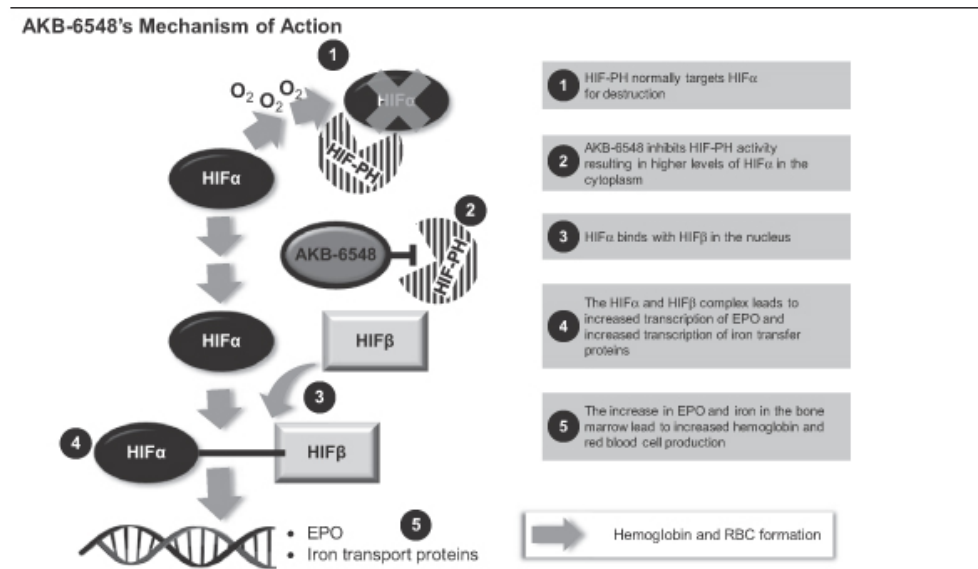
and improved stabilization of the bone marrow's iron supply, which ensures the proper incorporation of iron into hemoglobin necessary for such RBC production. This adaptive simulation is very similar to the natural response that is induced when a person ascends in altitude. At higher altitudes, low levels of oxygen circulating in the blood stream lead to reduced HIF-PH activity in relevant cells in the kidney and liver. The reduced HIF-PH activity stabilizes and increases levels of HIF $\alpha$  proteins (HIF1 $\alpha$  and HIF2 $\alpha$ ) in these cells. For most cells, the stabilization of HIF2 $\alpha$  is greater than that of HIF1 $\alpha$ , ultimately leading to an increase in EPO secretion and a subsequent increase in RBC production.

HIF-PH inhibitors work by blocking the effect of the prolyl-hydroxylase enzymes, which promote the breakdown of HIF $\alpha$  proteins. As the breakdown is inhibited, the level of these HIF $\alpha$  proteins increases in cells. These HIFs are the primary protein mediators that enable the body and all of its individual cells to adapt to changes in levels of oxygen. Both HIF1 $\alpha$  and HIF2 $\alpha$  proteins are consistently produced and their levels in cells are adjusted by the activity of the HIF-PH enzymes, which target the HIF $\alpha$  proteins for degradation. HIF1 $\alpha$  helps cells survive under very low oxygen conditions, whereas HIF2 $\alpha$  helps cells and the body to adapt to modest changes in oxygen, such that would occur with a change in altitude from sea level to up to 7,500 feet.

When HIF $\alpha$  is stabilized, it travels to the nucleus of the cell, where it binds to the protein HIF $\beta$ . When bound together, they induce the genetic signal for the production of EPO and several other proteins. The HIF-PH inhibitors increase HIF $\alpha$  levels in much the same way that a reduction in oxygen increases HIF $\alpha$  levels by inhibiting the HIF-PH enzymes in the body. With continued stabilization of HIF $\alpha$  (either by staying at higher altitude or by daily dosing of the HIF-PH inhibitor), the level of hemoglobin and RBCs will rise in order to increase the amount of oxygen circulating in the blood. In this way, once-daily dosing of AKB-6548 may have the potential to restore the normal level of EPO for a patient with anemia.

AKB-6548, our lead compound in development, works by inhibiting HIF-PH, leading to stabilization and increased levels of HIF $\alpha$ , and improved production of hemoglobin and RBCs, while maintaining normal levels of EPO in patients. In addition, we believe that AKB-6548's mechanism of action provides for the ability to induce a more prominent HIF2 $\alpha$  response (as naturally occurs with a moderate increase in altitude), and an enhancement in the normal diurnal variation of EPO, which is the normal rise and fall of EPO during the each day.

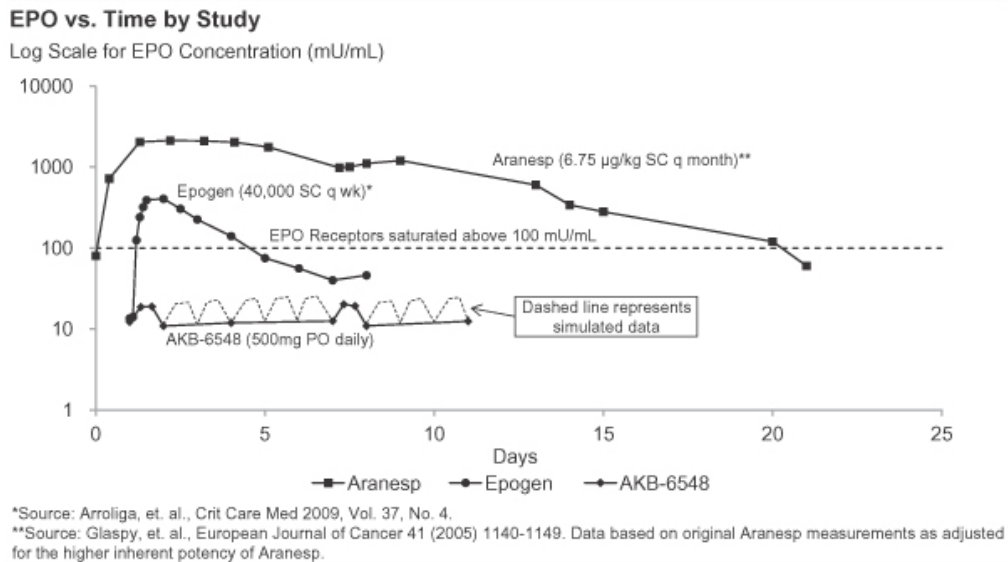
This mechanism of action is illustrated in the graphic below.



**Potential Best in Class Profile**

We believe AKB-6548 has compelling clinical data demonstrating a best in class profile with several potential safety and efficacy advantages over current injectable rESA therapy in the treatment of anemia secondary to CKD.

- *AKB-6548 significantly increases hemoglobin in anemic CKD patients.* We have successfully completed a Phase 2a trial, in which AKB-6548 significantly increased hemoglobin levels compared to baseline in a dose-dependent manner across all treatment arms ( $p < 0.0001$ ). Further, AKB-6548 provides a physiologic reticulocyte, or newly formed RBC, response, which leads to a more gradual and consistent increase in hemoglobin levels than what is seen with injectable rESA therapies, meaning that these improvements occur without causing patients' hemoglobin to rise to levels that cause concern.
- *AKB-6548 may have the potential to restore the normal diurnal variation of EPO for a patient with anemia in a way that an injectable rESA cannot.* Instead of binding directly to and saturating the EPO receptor for prolonged periods of time as is the case with current injectable rESA treatments, AKB-6548 acts by simulating the body's natural response to hypoxia that is carried out by stabilization of HIFa. We believe the manner in which AKB-6548 works permits a more prominent HIF2a response (as naturally occurs with a moderate increase in altitude) and there is an enhancement in the normal diurnal variation in EPO, which is the normal rise and fall of EPO during the each day, without continuous elevation of EPO levels. The graph below illustrates the EPO levels that are obtained with AKB-6548 compared with doses of Aranesp and Epogen.



- *Oral, once-daily dosing.* Once daily, oral dosing of AKB-6548 offers improved convenience for patients as compared to injectable rESAs. This convenience may increase access to anemia therapy for the largely underserved population of patients with anemia secondary to CKD who are not yet on dialysis and for patients with other forms of anemia, such as IAA. AKB-6548 offers the potential of flexible oral dosing that provides a more gradual and reliable means of titration than that of injectable rESAs.

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- *Ability to stabilize the iron supply to the bone marrow while improving hemoglobin production.* In clinical trials, AKB-6548 has demonstrated a dose-related increase in total iron binding capacity, or TIBC.
- These results indicate that AKB-6548 will stabilize the iron supply to the bone marrow while improving hemoglobin production and should improve EPO responsiveness. As a result, unlike injectable rESAs, which have no effect on iron mobilization, AKB-6548 offers the added potential benefit of reducing the amount of supplemental iron required by anemia patients.
- *Differentiated safety profile.* AKB-6548's novel mechanism of action and dosing profile offer the opportunity to potentially avoid the black box label ascribed to injectable rESAs. In our recently completed Phase 2a study, no drug-related serious adverse events were reported. Dosing was well-tolerated and there was no evidence of undesirable vascular response.

### **AKB-6548 Clinical Development Overview**

#### **Early Clinical Studies (CI-0001 to CI-0004, and CI-0006):**

An IND was filed for AKB-6548 for the treatment of anemia associated with CKD and chronic renal failure on July 17, 2009. Under the IND, we may investigate AKB-6548 in subjects who are not on dialysis and in subjects who are on dialysis. To date, AKB-6548 has been studied in eight clinical trials across four separate patient populations: healthy volunteers and patients with CKD stages 3, 4, and 5 (non-dialysis). These clinical trials consisted of four Phase 2a clinical trials and four Phase 1 clinical trials. The early clinical studies (CI-0001 through CI-0004) for AKB-6548 were designed to demonstrate the efficacy and safety of the compound, starting in healthy male volunteers and progressing to CKD patients with anemia. In healthy males, we demonstrated that AKB-6548 can be dosed daily, and that it induces the desired pharmacodynamics effect, specifically:

- the induction of enhanced diurnal EPO secretion from a single dose;
- an increase in new RBC production by day 5 of dosing; and
- an increase in hemoglobin levels by day 10 of dosing.

Subsequently, we demonstrated a similar induction of a diurnal EPO response in CKD patients. This was followed by a 28 day, dose-titration study to establish the necessary dosing information for increasing hemoglobin levels. Throughout these studies, AKB-6548 was generally well tolerated. There were no serious adverse events, or SAEs, and treatment emergent adverse events, or TEAEs, were limited in number and duration.

The most common potentially drug-related adverse events, or AEs, in our eight clinical trials were gastro-intestinal disorders, including diarrhea, nausea and constipation. In our CI-0001 trial, there was one subject who had diarrhea that was considered potentially related to the study drug. In our CI-0002 trial, the potentially drug-related TEAEs were gastroesophageal reflux and dyspepsia, each reported in separate subjects. In our CI-0006 trial, three of the eight subjects in the capsule group reported potentially drug-related AEs (nausea in two subjects and headache and dizziness in one subject each), and one of the eight subjects in the tablet group reported potentially drug-related headache and dizziness. In our CI-0003 trial, five subjects experienced AEs that were considered potentially drug-related. Two subjects had nausea. Other potentially drug-related AEs that were noted once included tachycardia, vomiting, pyrexia, upper respiratory tract infection, hypomagnesemia, myalgia, headache, somnolence, tremor, oropharyngeal pain, cold sweat and hypotension. In our CI-0004 trial, three subjects had potentially drug-related TEAEs, including nausea, chills, peripheral neuropathy, peripheral sensory neuropathy and muscle spasms. In our CI-0005 trial, the most frequently reported TEAEs considered to be potentially drug-related were gastrointestinal disorders, including one subject with abdominal discomfort, three subjects with constipation, one subject with diarrhea and two subjects with nausea. Other one-time events in the CI-0005 trial that were considered to be potentially drug-related included neutropenia, cardiac palpitations, decreased transferrin saturation, muscle spasms, dizziness, pollakiuria, hypertension and abnormal hair texture.

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The individual design and summary results of each of our completed clinical trials are highlight below:

Study	Study Design			Subjects Treated		Key Findings
	Subject	Design	Dose, Duration <sup>1</sup>	AKB-6548	Placebo	
<b>Phase 1</b> CI-0001	Healthy males	Double-blind, placebo-controlled, fasted	80 mg, 160 mg, 300 mg, 600 mg, 900 mg, 1200 mg; single dose	6 (80 mg) 6 (160 mg) 6 (300 mg) 6 (600 mg) 6 (900 mg) 6 (1200 mg)	12 (2 per cohort)	AKB-6548 was well tolerated, and dose responsive increases in EPO levels were demonstrated following a single dose. Half-life of the compound was measured at approximately 4.8 hours. Ten subjects had an AE (seven in the AKB-6548 group and three in the placebo group). No SAEs were reported.
CI-0002	Healthy males	Double-blind, placebo-controlled, fasted	500 mg, 700 mg, 900 mg; 10 days	8 (500 mg) 9 (700 mg) 8 (900 mg)	9 (3 per cohort)	AKB-6548 was well tolerated, and dose responsive increases in reticulocytes and hemoglobin levels were demonstrated. It was also shown that EPO levels returned to baseline by 24 hours following each dose. 26 subjects reported a TEAE. These were evenly distributed across dosing groups. No SAEs were reported.
CI-0006	Healthy males	Randomized, cross-over bioavailability study, fasted	315 mg; single dose of capsule and tablet, with three days between doses	8	0	Both capsules and tablets were well tolerated following a single dose, and shown to be bioequivalent. Six subjects had AEs considered related to study drug. No SAEs were reported.
<b>Phase 2</b> CI-0003	CKD, Stages 3 & 4	Open-label, fed	500 mg; single dose	22	0	Following a single dose of 500 mg of AKB-6548, the changes in EPO levels followed a similar pattern as that observed in the Phase 1 study at 600 mg in healthy volunteers (CI-0001). In these subjects with CKD, peak levels of EPO were similar to healthy male volunteers, and the half-life was modestly longer at 7.9 hours. Dosing was well tolerated. Five subjects had AEs considered related to study drug. No SAEs were reported.
CI-0004	CKD, Stages 3 & 4	Open-label	Within subject, dose escalation (potential doses of 200 mg, 300 mg, 400 mg, 500 mg, 600 mg, and 700 mg); 28 days of dosing	10	0	In this study, subjects started at 300 mg (CKD 4) or 400 mg (CKD 3). Dose adjustments could be made weekly based on reticulocyte count and hemoglobin data. Dosing was well tolerated. Average hemoglobin levels rose from 9.91 g/dL at baseline to 10.54 g/dL by Day 29. Three subjects had TEAEs considered related to study drug. No SAEs were reported.
CI-0005	CKD, Stages 3, 4 & 5, not on dialysis	Double-blind, placebo-controlled	240 mg, 370 mg, 500 mg, 630 mg; 42 days of dosing	18 (240 mg) 18 (370 mg) 17(500 mg) 19 (630 mg)	19	Dosing was well tolerated. AKB-6548 significantly increased hemoglobin levels in subjects compared to baseline in all dose groups and compared to placebo. The hemoglobin increase occurred without increasing pre-dose EPO levels (prior to daily AKB-6548 dose). Ten subjects had AEs considered related to study drug. There were eight reported SAEs in separated subjects which were all considered unrelated to study drug.
CI-0008	Healthy volunteers	Mass Balance	650 mg; single dose	6	0	Though the final study report is not yet complete, the preliminary data supported earlier findings from human and animal studies. The drug was generally well tolerated during this study.
CI-0009	End-stage renal disease (ESRD)	Pharmacokinetics	450 mg dose four hours prior to start of a dialysis session; 450 mg dose two hours after completion of a different dialysis session	12	0	During the study, dosing of the drug was well tolerated, and there was only one SAE, which was considered unrelated to AKB-6548.

<sup>1</sup> All doses were administered orally, once-daily.

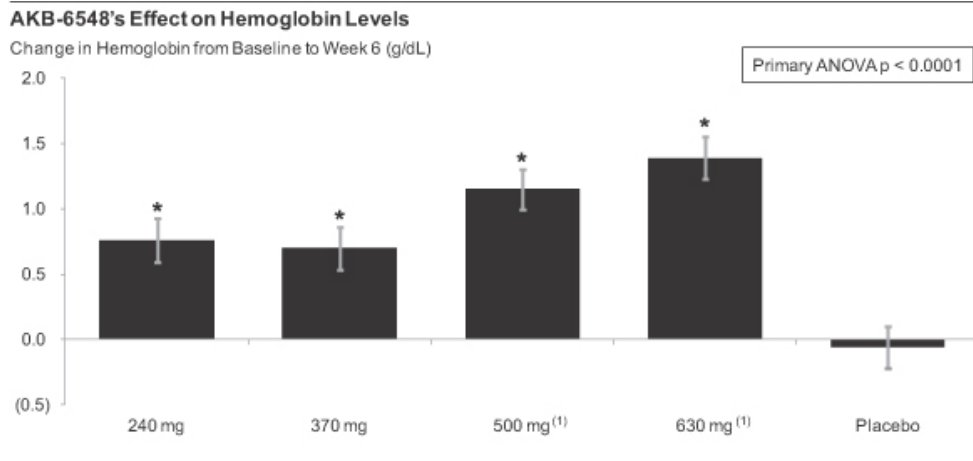
**CI-0005: Positive Phase 2a Proof of Concept Trial**

CI-0005 was designed to confirm the findings of the early clinical studies and to demonstrate efficacy in CKD patients. In November 2012, we presented at the American Association of Nephrology the results of a randomized, double-blind, placebo controlled trial of AKB-6548 in patients with CKD stages 3, 4 and 5 (not on dialysis) to evaluate the change in hemoglobin levels over 42 days at multiple dose levels. The study enrolled 93 patients with CKD stages 3, 4, or 5 (not on dialysis) who initiated treatment with either placebo or AKB-6548 in the following dose groups: 240 mg, 370 mg, 500 mg, or 630 mg once-daily for 42 days. Depending upon hemoglobin response, patients may have had their initial dose titrated to avoid too rapid of a rise in hemoglobin levels.

The primary endpoint for the trial was mean absolute change in hemoglobin from baseline. As shown in the first graphic below, the study results show all doses of AKB-6548 increased hemoglobin significantly compared with placebo in both the modified intent to treat, or MITT, population and the per protocol, or PP, population. A one-way analysis of variance, or ANOVA, test showed a statistically significant increase in mean absolute hemoglobin from baseline to week 6 for treatment compared with placebo ( $p < 0.0001$ ) in both the MITT and PP populations. The 95% simultaneous confidence limits for the four AKB-6548 treatment groups all showed significant increases in mean absolute hemoglobin from baseline to week 6.

At Day 42, AKB-6548 significantly increased hemoglobin levels in a dose-dependent manner compared to baseline in all dose groups. Important findings included:

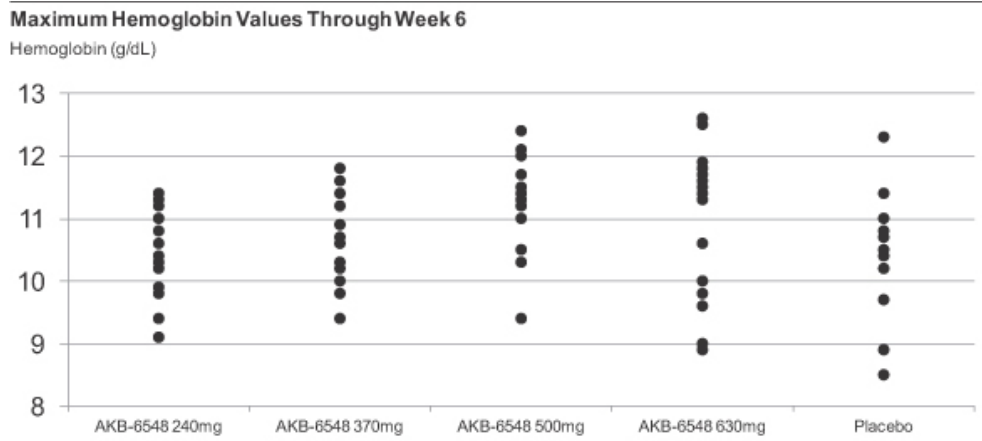
1. AKB-6548 treated patients experienced a statistically significant mean increase in hemoglobin, ranging from 0.7 to 1.4 g/dL by Day 42, while placebo-treated patients experienced a small mean decrease in hemoglobin of 0.1 g/dL. The average baseline hemoglobin level was 9.8 g/dL.



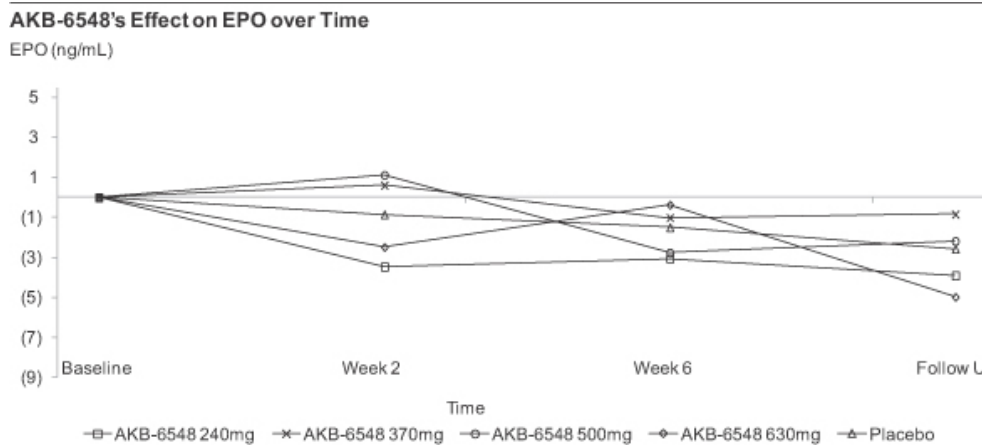
(1) 25% of patients in 630mg and 10% of patients in 500mg had their doses reduced by Week 4.

\* Two tailed paired t-test of Hemoglobin: Baseline vs. Week 6  $p < 0.01$ .

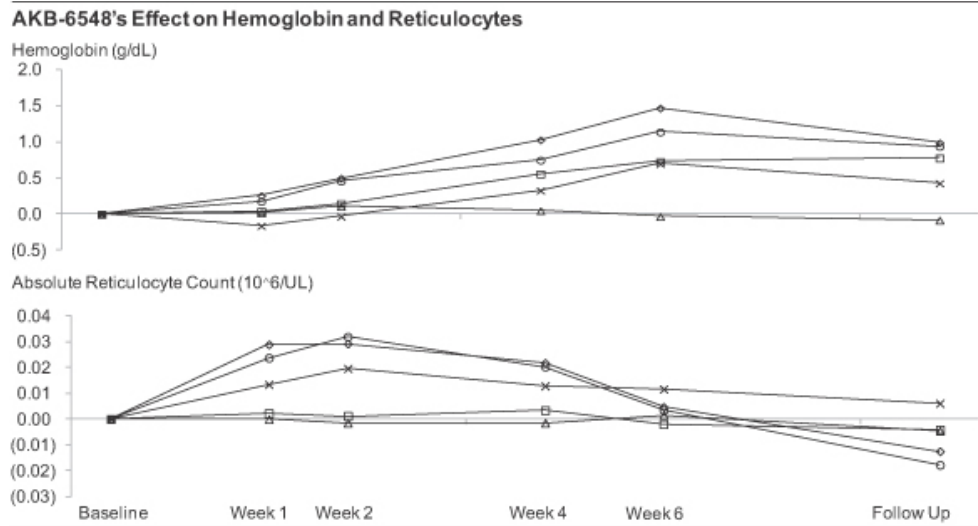
- No patient's measured hemoglobin level exceeded 13 g/dL throughout the study period.



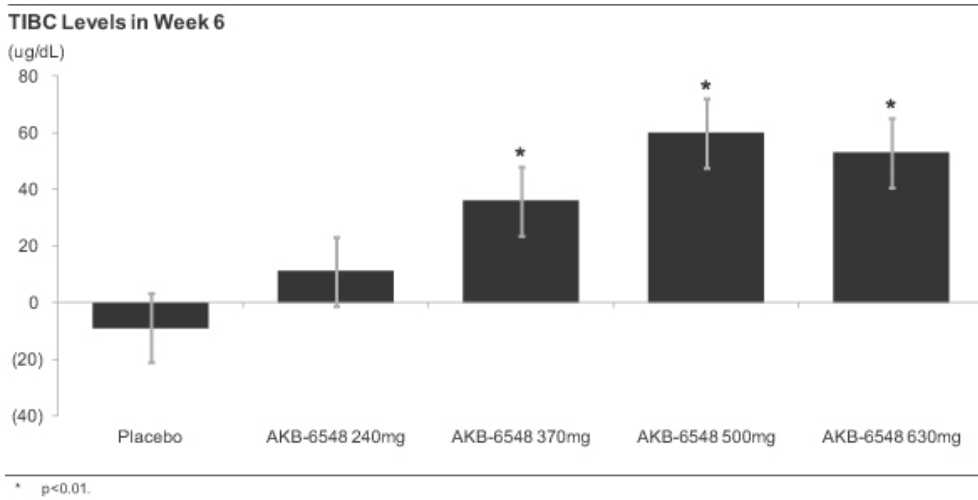
- The dose-dependent increases in hemoglobin occurred even though 26% of patients in the 630 mg dose and 11% of patients in the 500 mg dose decreased their dose, per protocol, as a result of a hemoglobin increase of greater than 1.5 g/dL or more by Day 28.
- The increase in hemoglobin levels occurred without increasing pre-dose EPO levels (prior to daily AKB-6548 dose), demonstrating that AKB-6548 is able to improve RBC production without chronically elevating the body's EPO levels.



5. The increase in hemoglobin levels was preceded by an increase in reticulocytes showing that an increase in hemoglobin levels is a result of a physiologic increase in RBC production.



6. A dose-related increase in TIBC indicated enhanced ability to stabilize the iron supply to the bone marrow while improving hemoglobin production, as shown below with the dose-dependent increase in TIBC.



AKB-6548 was generally well tolerated in the 91 subjects who received study drug. In total, 45 subjects had an AE: 34 (47.2%) in the AKB-6548 groups and 11 (57.9%) in the placebo group. AEs were evenly distributed across the dosing groups with no apparent dose related effect. Ten subjects (13.9%) treated with AKB-6548 and one placebo subject (5.3%) had AEs that were considered study drug related.

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with non-ST elevation myocardial infarction, hypertensive crisis, ventricular pacemaker lead replacement, and azotemia (uremia). One subject, who we believe received only three or four doses of study drug, died after being hospitalized for uremia. The subject's death occurred several days into her hospitalization following an in-hospital procedure when she developed sustained ventricular tachycardia and cardiac arrest. The subject's death was not considered to be related to AKB-6548. All other subjects recovered.

The principal investigator at the enrolling site for the subject experiencing the SAE is responsible for determining whether a SAE is related to AKB-6548 or not. If the principal investigator is able to determine an alternative reason for the cause of the SAE, then the SAE is generally considered to be unrelated. Upon continuing review of all SAEs from the various clinical studies, a pattern of SAEs may emerge to indicate relatedness. To date, no such pattern has emerged in our AKB-6548 trials.

VEGF is necessary for the maintenance of healthy kidney function and is regulated by HIF1a. Clinical studies have shown that increased VEGF levels are potentially linked to increased growth of tumors in patients with cancer. AKB-6548 provides for the ability to induce a more prominent HIF2a response, and consistent with this mechanism, no statistically significant change in VEGF levels were observed from baseline for any of the AKB-6548 dose groups.

We also found no statistically significant change in inflammation (C-reactive protein), renal function (Cystatin-C), heart rate, blood pressure and EKG values (including QT assessments).

### **Ongoing and Planned Clinical Trials**

#### ***Phase 2b Study (CI-0007)***

We are currently enrolling a Phase 2b study of AKB-6548 in subjects with anemia (hemoglobin  $\leq$  10.5 g/dL) secondary to CKD not requiring dialysis. This double-blind, randomized, placebo controlled study will evaluate the efficacy and safety of AKB-6548 in 200 subjects across 62 U.S. sites. The study will enroll patients who have never received rESA therapy, patients previously treated with rESAs, and patients actively treated with rESAs. Patients will initiate treatment with either 450mg of AKB-6548 or placebo once-daily for 20 weeks. The dose of AKB-6548 will be adjusted in accordance with the patient's hemoglobin response. The primary purpose of this study is to demonstrate an adaptive approach to dosing AKB-6548 that will enable subjects to appropriately raise their hemoglobin from baseline without excessive excursions to greater than 13.0 g/dL. Subjects will be extensively evaluated for clinical and laboratory safety, changes in specific biomarkers, and changes in quality-of-life and neuro-cognitive outcomes. We expect that the results for CI-0007 will enable the final design for Phase 3 studies of AKB-6548. It is anticipated that CI-0007 will be fully enrolled by the second quarter of 2014, and we expect that top line results will be announced in the fourth quarter of 2014.

Patients will be assigned in a double-blind fashion in a 2:1 ratio to either AKB-6548 or placebo. After initiating treatment at 450 mg, the dose will be adjusted in accordance with the protocol defined "Dose Adjustment Guidelines and Algorithm." We will determine optimal dosage, which includes tablet size and number of tablets per dose, and dose adjustment for the Phase 3 studies based on the results from the Phase 2b study. We do not currently anticipate that the range of doses will be significantly changed, but we plan to optimize the algorithm to help maintain hemoglobin in an acceptable range (likely 10.5 to 12 g/dL, subject to review and acceptance by FDA and other regulatory authorities). We plan to further adjust the algorithm to help minimize hemoglobin fluctuation and reduce the frequency of excessive excursions in hemoglobin.

The primary endpoint of our study is the percent of subjects who either (i) achieve or maintain a mean hemoglobin of  $\geq$  11.0 g/dL, or (ii) increase their hemoglobin by  $\geq$  1.2 g/dL over their pre-dose average hemoglobin between screening and baseline. Subjects who receive injectable rESA or transfusion rescue will be counted as failures and subjects receiving transfusion for a non-rescue reason will be removed from the primary



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analysis. Patients will also be analyzed for safety, including AEs, vital signs, electrocardiograms, and laboratory assay results.

Additional assessments to be conducted during our Phase 2b study include: iron metabolism (changes from baseline in iron, transferrin saturation (TSAT), TIBC, and ferritin); the dose of iron replacement needed to maintain iron levels; actual values and change from baseline in reticulocyte hemoglobin content, HbA1c, and lipids; functional biomarkers; concentration measurements of AKB-6548 and its glucuronide metabolite and measures of neurocognitive functioning and patient reported outcomes.

### ***Studies of AKB-6548 in Dialysis Patients***

We plan to initiate a multiple dose, open label Phase 2 study in approximately 60 subjects on dialysis in the first half of 2014. The primary endpoint will compare the change in hemoglobin from baseline for two different doses of AKB-6548 given once daily following hemodialysis: 1) 450 mg per dose and 2) 300 mg per dose. The first analysis of change in hemoglobin will be carried out at Week 8, and the second analysis will assess the subsequent change in hemoglobin with dose adjustment starting at Week 8. Key secondary endpoints will include (i) the safety of AKB-6548 in ESRD subjects on dialysis; (ii) the total dose of IV iron therapy for the eight weeks prior to baseline to the first (Weeks 1-8) and second (Weeks 9-16) eight weeks of treatment; and (iii) the effect of dialysis on the pharmacokinetics of AKB-6548.

### ***Projected Phase 3 Clinical Trials***

Upon completion of our Phase 2b study, and if we receive positive feedback from the FDA, we intend to initiate our Phase 3 studies. We expect that the endpoints, duration, and size of these Phase 3 trials will be based on those used in the Omontys (Peginesatide) approval studies, with modifications to adjust for the shift in focus to CKD in patients not on dialysis, because Omontys was the most recently approved new drug for the treatment of anemia secondary to CKD. Though the primary endpoint for all of the Omontys studies was based on hemoglobin, the total size and duration of the studies were determined by the principal secondary outcome, which was an index of cardiac safety events, or CSEs. The key difference between the clinical program for Omontys and AKB-6548 is that the Omontys trial was primarily designed around patients on dialysis, with only one-third of the subjects being those who were not on dialysis. As a result, the overall rate of CSE events in the Omontys studies is considerably higher than the rate anticipated for AKB-6548 for subjects not on dialysis. Therefore, we believe that approval for AKB-6548 in non-dialysis subjects will require a non-inferiority limit that is higher than the 1.3 required for Omontys for both dialysis and non-dialysis subjects. The endpoints have not yet been agreed upon with FDA or other regulatory bodies.

The primary two studies will be double-blind, randomized, and placebo controlled. The anticipated goal of anemia management in these studies will be to raise hemoglobin levels to greater than 10.5 g/dL and include a rescue component for subjects with declining hemoglobin that uses injectable rESAs in accordance with existing guidelines. In this manner, AKB-6548 will be compared to the existing standard of care for both efficacy and safety. The principle requirement for safety will be to demonstrate non-inferiority for cardiovascular safety of AKB-6548 relative to the standard of care provided to the placebo group. We are designing these clinical studies to be applicable for global development with limited protocol differences between geographic regions. The total number of subjects to be enrolled in the Phase 3 studies will be determined upon agreement with FDA, EMA and other regulatory authorities.

Although the exact size and timing cannot be known until final agreement is reached with the FDA, EMA and other regulatory authorities, we estimate that the Phase 3 studies for the indication of anemia secondary to CKD (not including dialysis) will require approximately three studies and include a total of 2,000 subjects. We estimate that the studies will be two years in duration, with an average subject duration on study drug of 1.25 years.

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### **Additional Studies**

Prior to initiating the Phase 3 studies, we intend to complete a thorough QT, or TQT, study in accordance with FDA guidance to ensure that AKB-6548 does not affect the cardiac conduction cycle. A lengthened QT interval is a biomarker for certain ventricular arrhythmias and a risk factor for sudden death. To date, AKB-6548 has not shown any tendency to affect the QT interval either in humans or animals. We initiated this study in approximately 50 normal volunteers in January 2014.

To test AKB-6548 in a chronic dosing setting, carcinogenicity assessments in two rodent species (rat and mouse) will be pursued. AKB-6548 has been shown to be orally bioavailable and pharmacologically active in both species. The results of a standard battery of tests that evaluate for mutations in cells or animals have indicated that AKB-6548 does not cause mutations that could lead to cancer. However, to satisfy the expected regulatory requirement, two-year carcinogenicity assessments in each of the two rodent species will be conducted. Completion of three-month (mouse; ongoing) and six-month (rat; completed) oral toxicity evaluations will support dose selection for the respective two-year carcinogenicity assessment.

Finally, in order to complete the registration package for drug approval, we are exploring the need to evaluate specific drug interactions with patients taking AKB-6548, as patients with CKD take multiple medications. It is likely we will conduct at least one of these additional clinical studies.

### **Additional Indications**

The two major additional indications for AKB-6548 are anemia associated with aging (also known as IAA) and anemia secondary to congestive heart failure, or CHF. AKB-6548, with its different mechanism of action, offers a completely new approach to these large markets. Both occur in very large segments of the population and are associated with considerable morbidity and mortality. Anemia affects approximately 10% of individuals age 65 and over, and in those individuals age 85 and older, the percentage is greater than 20%, according to a paper published in 2004 in the peer-reviewed journal *Blood*. Of these, approximately one-third are considered to be IAA. Other causes of anemia in this population include CHF, CKD and nutritional deficiencies. Because injectable rESAs are currently associated with increased cardiovascular events, they have not been successful entering either of these markets.

We anticipate studying both indications by using a fixed, low-dose therapeutic approach which would enable a modest increase in hemoglobin, and minimize the requirement for follow-up assessments. Although we will have extensive dosing information from the CKD studies, additional Phase 2 studies will need to be performed to evaluate the required dose level. In addition, the Phase 2 studies will evaluate cardiac performance and other outcomes that will be critical in Phase 3. It is likely that the study in IAA would be undertaken first, as the mechanism of action of AKB-6548 is well supported by the scientific literature in IAA. Specifically, AKB-6548 is expected to stabilize the limited production of HIF2a in older patients. The primary outcome for this study will focus on quality-of-life outcomes, such as the ability of a subject to perform activities of daily living. In addition, the study will need to evaluate standard measures of morbidity and mortality. An IND has not been filed for AKB-6548 for the treatment of IAA. We expect to file this IND following the conclusion of the Phase 2b clinical trial for AKB-6548 in patients with anemia secondary to CKD who are not dependent on dialysis. We expect to initiate the study following the analysis of the Phase 2b study results, particularly the performance of the drug in patients over the age of 70.

### **AKB-6899**

AKB-6899, another HIFa-stabilizing compound, is a very close relative of AKB-6548. In screening AKB-6899 for its HIF-related properties, it was discovered that in cells cultured at low oxygen levels, AKB-6899 significantly inhibited the expression of VEGF and phosphoglycerate kinase, or PGK, mRNA, both of which are associated with the growth of cancerous tumors. In addition, AKB-6899 was found to significantly stimulate the

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production of soluble vascular endothelial growth factor receptor 1, or sVEGFr1. sVEGFr1 is known to be a potent inhibitor of VEGF signaling by sequestering VEGF and inhibiting its interaction with transmembrane receptors—in so doing, sVEGFr1 can inhibit the growth of certain types of cancer cells. AKB-6899 was also found to stimulate the production of EPO in a manner similar to AKB-6548.

These properties, and others, indicate that AKB-6899 may be an excellent treatment for certain cancers (ovarian, breast, colon, and possibly lung), that could be given in combination with other types of chemotherapy. In addition AKB-6899 may also be a candidate compound for the treatment of chemotherapy-induced anemia and for VEGF-related eye diseases. AKB-6899 has been used effectively in several animal models of cancer, both alone and in combination. In addition, it has been shown to be effective in animal models of colitis.

### **Manufacturing and Supply**

AKB-6548 is a small-molecule drug that is manufactured from readily available commercial starting materials. The manufacturing of AKB-6548 uses standard chemical technologies and equipment. The intended commercial manufacturing route has been successfully scaled up and has produced approximately 40 kg of AKB-6548 drug substance. The drug substance can be readily formulated into compressed tablets using standard USP grade excipients. We have made compressed tablets of varying sizes with no apparent effect on dissolution profile or bioavailability.

The preclinical candidate AKB-6899 has been produced on laboratory scale, but clinical or commercial manufacturing has not been investigated. Based on the similarity of the structure to AKB-6548, similar commercially available starting materials and commercial manufacturing process can be expected.

We have no internal manufacturing capabilities and rely on outside manufacturers to produce all lots of drug substance and drug products. On February 28, 2014, we entered into a master services agreement with Evonik Corporation, or Evonik, pursuant to which Evonik shall further develop and manufacture the drug substance for use in our Phase 3 development program of AKB-6548 and other clinical trials.

A high quality U.S.-based manufacturer will be selected to supply drug product for our Phase 3 development program of AKB-6548 and other clinical trials. Current tableting methods are amenable for scale up to commercial quantities of drug product. To date, AKB-6548 has been manufactured under strict cGMP regulations and we believe has fully complied with the FDA guidelines for the manufacture of drug substance and drug product used in clinical trials.

### **Intellectual Property**

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know-how are important to our business. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we may benefit from a variety of statutory frameworks in the United States, Europe and other countries that provide periods of non-patent-based exclusivity for qualifying molecules. See “—Regulatory Matters.”

Our commercial success will depend in part on obtaining and maintaining patent protection of our current and future product candidates, methods of their use and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. Even once patents successfully issue, third parties may challenge the validity, enforceability, inventorship, or scope thereof,

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which may result in such patents being narrowed, invalidated or held unenforceable. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

Our patent estate, on a worldwide basis, includes 19 allowed applications and issued patents and approximately 39 pending utility and provisional patent applications, with pending and issued claims relating to our current clinical stage candidate AKB-6548 as well as other product candidates, including AKB-6899. We also hold three patents that claim the crystal of a protein-ligand complex of EGLN-1 as well as methods for identifying compounds that bind to EGLN-1.

Individual patents extend for varying periods of time depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued from applications filed in the United States are effective for twenty years from the earliest non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, however, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also twenty years from the earliest international filing date. Our issued patents and pending applications with respect to our composition of matter, methods of treatment, and pharmaceutical compositions are expected to expire in 2027 or 2028 (depending on eligibility for patent term adjustment) and our pending applications with respect to processes for manufacturing AKB-6548, dosing regimens, formulations, and various other aspects relating to the treatment of anemia using AKB-6548 are expected to expire between 2032 and 2034, exclusive of possible patent term adjustments or extensions; however, the actual protection afforded by a patent varies on a product by product basis, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of extensions of patent term, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Changes in either the patent laws or interpretations of patent laws in the United States and other countries can diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that may be granted in our patents or in third-party patents. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our drugs and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own or may receive in the future, may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. The patent positions for our most advanced programs are summarized below.

### ***AKB-6548 Patent Portfolio***

We hold four issued patents and one pending application covering the composition of matter, method of treating anemia, and pharmaceutical compositions of AKB-6548 in the United States, one issued patent in Europe (registered in most countries of the European Patent Convention), and additional patents issued or pending in many other major jurisdictions worldwide, including Japan, China, South Korea, Brazil, Mexico, Russia, Israel and India. The expected expiration date for these composition of matter patents is 2027 plus any extensions or adjustments of term available under national law.

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In July of 2011, a third party filed an opposition to our issued European Patent No. 2044005 (the '005 Patent). During the oral proceedings, which took place on April 10, 2013, the Opposition Division of the European Patent Office maintained the '005 Patent on the basis of the third auxiliary request filed during the oral proceedings. This decision resulted in the maintenance of a claim directed to a compound chosen from a group of eight compounds, including AKB-6548, as well as claims to compositions and methods for treating various diseases, including, but not limited to, anemia. Both parties have appealed the decision of the Opposition Division and final resolution of the opposition proceedings will likely take a number of years. We cannot be assured of the breadth of the claims that will remain in the '005 Patent or that the patent will not be revoked in its entirety.

We also hold patents and patent applications directed to processes for manufacturing AKB-6548, dosing regimens, formulations, polymorphs, and various other aspects relating to the treatment of anemia using AKB-6548 that are expected to expire between 2032 and 2034 exclusive of possible patent term extensions.

### ***AKB-6899 Patent Portfolio***

We hold two issued patents and one pending application covering the AKB-6899 composition of matter and pharmaceutical compositions in the United States, and additional patents issued or pending in many other major jurisdictions worldwide, including Europe, Japan, China, South Korea, Brazil, Mexico, Russia and India. The expected expiration date for these composition of matter patents is 2027 plus any extensions or adjustments of term available under national law.

We hold one issued patent that covers the treatment of anemia by administration of AKB-6899, which is expected to expire in 2028. We also hold, either alone or jointly, three pending applications covering various methods, including, but not limited to, the treatment of cancer or chemotherapy-induced anemia by administration of AKB-6899 in the United States. The expected expiration dates for these method of treatment patent applications are expected to be either 2027 or 2032 exclusive of possible patent term extensions or adjustments.

### ***Know-How***

In addition to patents, we rely upon unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment provisions in the confidentiality agreements with our employees. These agreements are designed to protect our proprietary information and, in the case of the invention assignment provisions, to grant us ownership of technologies that are developed by our employees. These agreements may be breached, and we may not have adequate remedies for any breach.

To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

### ***Third Party Filings***

We are aware of certain U.S. patents issued to FibroGen, directed to, among other things, purportedly new methods of using previously known heterocyclic carboxamide compounds for purposes of treating or affecting specified conditions. We do not believe these currently issued, FibroGen U.S. patents conflict with our intellectual property rights; nor do we make any admission that any of such patents are valid or enforceable. Under U.S. law, a person may be able to patent a discovery of a new way to use a previously known compound, even if such compound itself is patented, provided, the newly discovered use is novel and nonobvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously

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known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method. We are not aware of any valid U.S. patents issued to FibroGen that claim methods of using any of our product candidates for purposes of inhibiting HIF-PHs for the treatment of anemia secondary to CKD.

In addition, we are aware of certain foreign patents owned by FibroGen. For example, in June 2013, the European Patent Office granted European Patent No. 1463823 (the '823 patent) to FibroGen. The '823 patent claims, among other things, the use of a heterocyclic carboxamide compound selected from the group consisting of pyridine carboxamides, quinoline carboxamides, isoquinoline carboxamides, cinnoline carboxamides, and beta-carboline carboxamides that inhibits HIF-PH enzyme activity in the manufacture of a medicament for increasing endogenous EPO in the prevention, pretreatment, or treatment of anemia. On December 5, 2013, we filed an opposition with the European Patent Office to the '823 patent requesting that the '823 patent be revoked in its entirety. While, for the reasons set forth in our opposition, we believe the '823 patent should be revoked in its entirety, the ultimate outcome of the opposition remains uncertain.

### **Competition**

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. These companies also have significantly greater research capabilities than us. Many universities and private and public research institutes are active in CKD research, some in direct competition with us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. The key competitive factors affecting the success of AKB-6548, if approved, are likely to be its efficacy, convenience and safety profile.

If AKB-6548 is approved and launched commercially, competing drugs will include EPOGEN and potentially Aranesp, which are both marketed by Amgen, Inc., or Amgen, in addition to Procrit and Eprex, which are marketed by Johnson & Johnson. Aranesp, introduced in 2001, has significant market share in the United States, particularly in the oncology and the non-dialysis markets, although it is approved for treatment in dialysis patients as well. In Europe, Roche has obtained regulatory approval to market, and has launched, a PEGylated rESA called Mircera. Mircera reportedly has greater plasma stability than any of the currently marketed products. PEG is a polymer that increases the time rEPO remains in the circulation and consequently can be dosed less frequently. Mircera has also obtained regulatory approval in the United States, but as a result of Roche and Amgen's patent infringement litigation, Mircera was found to infringe several U.S. patents owned by Amgen and has been enjoined from being sold in the United States until mid-2014 under the terms of a limited license. If Mircera enters the U.S. market, we believe it will be in direct competition with AKB-6548 because of Mircera's ability to be long-acting; therefore, it could potentially limit the market for AKB-6548.

We may also face competition from potential new anemia therapies if we obtain approval for and commercially launch AKB-6548. There are several other HIF product candidates for anemia indications in various stages of development by potential competitors. These candidates are being developed by companies such as FibroGen, Japan Tobacco, AstraZeneca, GlaxoSmithKline and Bayer, all of whom are likely to have greater financial resources than our company. FibroGen, in particular, is ahead of us in the clinical development of its product, FG-4592 (roxadustat). Such HIF compounds under development may have a mechanism of action that is the same or similar to AKB-6548 and promote the production of naturally occurring EPO in patients. Some of these product candidates may enter the market as early as 2015 or 2016. If these product candidates enter the market, they may compete with AKB-6548, if it is approved and marketed.

In addition, certain companies are developing potential new therapies for renal-related diseases that could potentially reduce rESA utilization and thus limit the market for AKB-6548 if it is approved and marketed.

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The introduction of biosimilars into the rEPO market in the United States will constitute additional competition for AKB-6548 if it is approved and marketed. A biosimilar product is a subsequent version of an existing, branded biologic product. The patent for the existing, branded product must expire in a given market before biosimilars may enter that market. The patents for epoetin alfa, a version of rEPO, expired in 2004 in the European Union, and the remaining patents have expired or will expire in 2012 through 2015 in the United States. Several biosimilar versions of rEPO are available for sale in the European Union and biosimilar versions of rEPO are currently being studied in clinical trials in the United States.

For example, in January 2012, Hospira, Inc. announced the beginning of its Phase 3 clinical program for its biosimilar rEPO with results anticipated in 2013, and in October 2012, Sandoz announced the beginning of its Phase 3 clinical program for its biosimilar rEPO with results anticipated in 2014. Upon entry into the U.S. market, biosimilars will compete with AKB-6548 if it is approved and marketed, and will likely drive down prices for rEPO, which could also adversely affect our reimbursement.

In the dialysis market, it is typical to compete for and enter into long-term supply agreements with the major operators of dialysis clinics in the United States. In particular, two of the largest operators of dialysis clinics in the United States, DaVita Inc., or DaVita, and Fresenius, account for more than half of the rESA sales in the U.S. dialysis market. Both DaVita and Fresenius entered into a long-term supply agreement with Amgen that began in January 2012. We believe that it may be challenging to enter into or expand upon long or short-term supply agreements with DaVita, Fresenius or other operators of dialysis clinics.

### **Regulatory Matters**

The FDA and comparable regulatory authorities in state and local jurisdictions and in other countries impose substantial and burdensome requirements upon companies involved in the clinical development, manufacture, marketing, labeling and packaging storage, distribution, post-approval monitoring and reporting, advertising and promotion, pricing and export and import of drugs. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Moreover, failure to comply with applicable regulatory requirements may result in, among other things, warning letters, clinical holds, civil or criminal penalties, recall or seizure of products, injunction, disbarment, partial or total suspension of production or withdrawal of the product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

#### ***U.S. Government Regulation***

In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA's implementing regulations. If we fail to comply with applicable FDA or other requirements at any time during the drug development process, clinical testing, the approval process or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any FDA enforcement action could have a material adverse effect on us. FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States.

The process required by the FDA before a drug may be marketed in the United States generally involves:

- completion of extensive nonclinical laboratory tests, nonclinical animal studies and formulation studies performed in accordance with the FDA's current Good Laboratory Practice, or cGMP, regulations;
- submission to the FDA of an IND application which must become effective before human clinical trials in the United States may begin;
- approval by an IRB or ethics committee at each clinical trial site before each trial may be initiated;

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- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug candidate for each proposed indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current cGMP regulations;
- satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or commercial shipment of the drug in the United States.

The nonclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. Nonclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product.

The results of nonclinical tests, together with manufacturing information, analytical data and a proposed clinical trial protocol and other information, are submitted as part of an IND to the FDA. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. Some nonclinical testing may continue even after the IND is submitted, but an IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Accordingly, submission of an IND may or may not result in the FDA allowing clinical trials to commence. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators in accordance with cGCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be used. Each protocol must be submitted to the FDA as part of the IND. In addition, an independent IRB or ethics committee for each medical center proposing to conduct a clinical trial must also review and approve a plan for any clinical trial before it can begin at that center and the IRB must monitor the clinical trial until it is completed. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA so long as the clinical trial is conducted in compliance with an international guideline for the ethical conduct of clinical research known as the Declaration of Helsinki and/or the laws and regulations of the country or countries in which the clinical trial is performed, whichever provides the greater protection to the participants in the clinical trial.

### ***Clinical Trials***

Clinical trials are typically conducted in three or four phases, which may overlap or be combined:

- Phase 1: Clinical trials are initially conducted in a limited population of subjects to test the drug candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients with severe problems or life threatening diseases to gain an early indication of its effectiveness.



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- Phase 2: Clinical trials are generally conducted in a limited patient population to evaluate dosage tolerance and appropriate dosage, identify possible adverse effects and safety risks, and evaluate preliminarily the efficacy of the drug for specific targeted indications in patients with the disease or condition under study.
- Phase 3: Clinical trials are typically conducted when Phase 2 clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile. Phase 3 clinical trials are commonly referred to as “pivotal” studies, which typically denotes a study which presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a drug. Phase 3 clinical trials are generally undertaken with large numbers of patients, such as groups of several hundred to several thousand, to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites.
- Phase 4: In some cases, FDA may condition approval of an NDA for a product candidate on the sponsor’s agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post-approval to gain more information about the drug. Such post approval trials are typically referred to as Phase 4 clinical trials.

The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a DSMB or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. A sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the drug in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

### ***New Drug Applications***

The results of nonclinical studies and of the clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use.

Once the NDA submission has been accepted for filing, under the Prescription Drug User Fee Act (PDUFA), the FDA has a goal of responding to standard review NDAs within ten months after the 60-day filing review period, but this timeframe is often extended. The first indication of the FDA’s review progress is provided at the mid-cycle review. This typically occurs five months after the NDA is submitted. However, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an application, the FDA will inspect the facility or the facilities at which the finished drug product, and sometimes the active drug ingredient, is manufactured, and will not approve the drug unless cGMP compliance is satisfactory. The FDA may also inspect the sites at which the clinical trials were conducted to assess their compliance, and will not approve the drug unless compliance with GCP requirements is satisfactory.

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After the FDA evaluates the NDA and conducts inspections of manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or other significant, expensive, and time-consuming requirements related to clinical trials, preclinical studies and/or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret data. The FDA could also approve the NDA with a REMS to mitigate risks, which could include medication guides, physician communication plans, or elements to ensure safe use, such as restricted distribution programs, patient registries or other risk minimization tools. The FDA may also condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

Once the FDA approves an NDA, or supplement thereto, the FDA may withdraw the approval if ongoing regulatory requirements are not met or if safety problems are identified after the drug reaches the market. Where a withdrawal may not be appropriate, the FDA still may seize existing inventory of such drug or require a recall of any drug already on the market. In addition, the FDA has the authority to prevent or limit further marketing of a drug based on the results of post-market studies or surveillance programs.

After regulatory approval of a drug is obtained, companies are subject to a number of post-approval requirements. For example, there are reporting obligations regarding certain adverse events received and production problems. Companies are also required to report updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. Drugs may be marketed only for the FDA approved indications and in accordance with the provisions of the approved labeling. The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. A company can make only those claims relating to safety and efficacy that are approved by the FDA. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional nonclinical studies and clinical trials. As with new NDAs, the review process is often significantly extended by the FDA requests for additional information or clarification. Also, quality control and manufacturing procedures must continue to conform to cGMP requirements after approval to ensure and preserve the long term stability of the drug product. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP requirements, which imposes extensive procedural, substantive and record keeping requirements. In addition, changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP requirement and other aspects of regulatory compliance.

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The testing and approval processes require substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. Even if we believe a clinical trial has demonstrated safety and efficacy of one of our drug candidates for the treatment of a disease, the results may not be satisfactory to the FDA. Nonclinical and clinical data may be interpreted by the FDA in different ways, which could delay, limit or prevent regulatory approval. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals which could delay or preclude us from marketing drugs. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of the drugs.

### ***Europe/Rest of World Government Regulation***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries.

Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application, or CTA, much like the IND prior to the commencement of human clinical trials. In Europe, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. To obtain regulatory approval of an investigational drug under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the NDA in the United States is similar to that required in Europe, with the exception of, among other things, country-specific document requirements.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with cGCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### ***Special Protocol Assessment***

An SPA is a written agreement with the FDA on the details of the design, size, execution and planned analysis for a clinical trial intended to form the primary basis of an effectiveness claim in an NDA. After the clinical trial begins, the agreement may only be changed through a written agreement between the sponsor and the FDA. An SPA is generally binding upon the FDA unless the FDA determines that there are public health concerns unrecognized at the time the SPA agreement was entered into, other new scientific concerns regarding product safety or efficacy arise, or if the sponsor fails to comply with the agreed-upon trial protocol. If the outcome of the clinical trial is successful, the sponsor will ordinarily be able to rely on it as the primary basis for approval with respect to effectiveness.

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### ***Fraud and Abuse Laws***

In the United States, the research, manufacturing, distribution, sale and promotion of drug products and medical devices are subject to regulation by various federal, state and local authorities in addition to the FDA, including the CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice, state Attorneys General, and other state and local government agencies.

These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, the PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes created by HIPAA. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Moreover, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal False Claims Act, which prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our stock price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the PPACA also imposed new reporting requirements on drug manufacturers for payments made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers were required to begin collecting data on August 1, 2013 and will be required to submit reports to CMS by March 31, 2014 (and by the 90<sup>th</sup> day of each subsequent calendar year).

In addition, many states have adopted laws similar to the federal laws discussed above. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid. There has also been a recent trend of increased federal and state regulation of payments made to physicians. Certain states mandate implementation of compliance programs, impose restrictions on drug manufacturers’ marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. Because we intend to commercialize

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products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we plan to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Due to the breadth of and ambiguities in these laws, the absence of guidance in the form of regulations or court decisions, and the potential for additional legal or regulatory change in this area, it is possible that our future sales and marketing practices and/or our future relationships with physicians might be challenged under these laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

### ***Third-Party Coverage and Reimbursement***

Sales of pharmaceutical products depend in significant part on the availability of coverage and adequate reimbursement by third-party payors, such as state and federal governments, including Medicare and Medicaid, and commercial managed care providers. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for AKB-6548 will be made on a payor by payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication. A decision by a third-party payor not to cover our product candidates could reduce physician utilization of our products once approved and have a material adverse effect on our future sales, results of operations and financial condition. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

### ***Healthcare Reform***

In March 2010, the PPACA was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. Among the provisions of PPACA of greatest importance to the pharmaceutical industry are the following:

- Effective in 2010, PPACA made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP.
- PPACA also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010 and by expanding the population potentially eligible for Medicaid drug benefits, to be phased-in by 2014. CMS has proposed to expand Medicaid rebate liability to the territories of the United States as well.
- In addition, PPACA provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by the CMS may also provide for the public availability of pharmacy acquisition cost data, which could negatively impact our sales.
- Effective in 2010, PPACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In addition, as 340B drug pricing is determined based on AMP and Medicaid

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rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could result in an increase in the required 340B discounts.

- Effective in 2011, PPACA imposed a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., “donut hole”).
- Effective in 2011, PPACA imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.
- As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to PPACA to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.
- PPACA created the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings.
- PPACA established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Many of the details regarding the implementation of PPACA are yet to be determined, and at this time, it remains unclear the full effect that PPACA would have on our business. In addition, we expect that additional state and federal healthcare reform measures will be adopted in the future. Because we anticipate that a significant proportion of patients eligible for AKB-6548 will be covered by Medicare Part D, any government healthcare reform measures which limit the amounts that federal and state governments will pay for healthcare products and services could result in reduced demand for our products once approved or additional pricing pressures.

### ***Other Regulations***

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

### **Employees**

As of December 31, 2013, we had 28 employees, 24 of whom were full-time, eight of whom hold Ph.D. or M.D. degrees, 16 of whom were engaged in research and development activities and 12 of whom were engaged in business development, finance, information systems, facilities, human resources or administrative support. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

### **Facilities**

Our corporate headquarters are located in Cambridge, Massachusetts. We currently lease approximately 6,837 square feet of office space in Cambridge, Massachusetts under a lease that expires on December 26, 2016.

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We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

**Legal Proceedings**

We have opposition proceedings pending in the Opposition Division of the European Patent Office. Final resolution of the opposition proceedings will likely take a number of years. For more information, see “Business—Intellectual Property.”

We are not currently a party to any other material legal proceedings.

## Management

### Executive Officers and Directors

Below is a list of the names, ages and positions of the individuals who serve as our executive officers and directors as of February 28, 2014.

<u>Name</u>	<u>Age</u>	<u>Position</u>
John P. Butler	49	President and Chief Executive Officer; Director
Jason A. Amello	45	Senior Vice President, Chief Financial Officer and Treasurer
Robert Shalwitz, M.D.	59	Chief Medical Officer
Nicole R. Hadas	41	Vice President, General Counsel and Secretary
Muneer A. Satter	53	Co-Chairman of the Board of Directors
Campbell Murray, M.D.*	37	Co-Chairman of the Board of Directors
Jack Nielsen	50	Director
Anupam Dalal, M.D.	42	Director
Giovanni Ferrara*	45	Director
Kim Dueholm, Ph.D.	51	Director
Duane Nash, M.D.	43	Director
Michael S. Wyzga	58	Director

\* Dr. Murray and Mr. Ferrara have notified the Company that they will resign from our board of directors immediately prior to the effectiveness of the registration statement.

**John P. Butler** joined Akebia as director in July 2013 and was appointed as the President and Chief Executive Officer of Akebia in August 2013. Prior to joining Akebia, from 2011 until 2013, Mr. Butler served as the Chief Executive Officer of Inspiration Biopharmaceuticals, Inc., a biopharmaceutical company that filed for protection under Chapter 11 of the U.S. Bankruptcy Code in October 2012 prior to the successful sale of its hemophilia assets to Cangene Corporation and Baxter International in early 2013. From 1997 to 2011, Mr. Butler held various positions at Genzyme Corporation, a biopharmaceutical company, most recently serving as President of the company's rare genetic diseases business. From 2002 until 2010, Mr. Butler led Genzyme's renal division. Prior to his work at Genzyme, Mr. Butler held sales and marketing positions at Amgen and Hoffmann-La Roche. Mr. Butler currently serves as the chairman of board of trustees for the American Kidney Fund and a member of the board of directors of Relypsa, Inc. Mr. Butler received a B.A. in Chemistry from Manhattan College and an M.B.A. degree from Baruch College, City University of New York. We believe that Mr. Butler is qualified to serve on our board of directors due to his industry experience in the biotechnology sector, particularly his experience working in the renal disease market.

**Jason A. Amello** joined Akebia as Senior Vice President, Chief Financial Officer and Treasurer in 2013. Prior to joining Akebia, Mr. Amello served as Executive Vice President, Chief Financial Officer and Treasurer of ZIOPHARM Oncology, Inc., a biopharmaceutical company, from 2012 to 2013. From 2000 to 2011, Mr. Amello held various positions at Genzyme Corporation, most recently as Senior Vice President, Corporate Controller and Chief Accounting Officer. Earlier in his career, Mr. Amello spent 10 years in the business advisory and assurance practice of Deloitte, serving in various roles of increasing responsibility through senior manager. Mr. Amello holds a B.A. from Boston College and is a Certified Public Accountant in the Commonwealth of Massachusetts.

**Robert Shalwitz, M.D.** co-founded Akebia in 2007. Prior to Akebia, Dr. Shalwitz was Vice President of Clinical Development at Reliant Pharmaceuticals, a biopharmaceutical company, from 2005 to 2007. From 1995 to 2005, Dr. Shalwitz was Medical Director at Abbott Labs. Prior to Abbott Labs, Dr. Shalwitz was an academic pediatric endocrinologist for 10 years, and his research at Washington University in St. Louis and at the Children's Hospital of Orange County (CA) focused on glucose and glycogen metabolism. Dr. Shalwitz received a B.G.S. from the University of Michigan and an M.D. from SUNY Buffalo.



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**Nicole R. Hadas** joined Akebia as Vice President, General Counsel and Secretary in 2013. Prior to Akebia, Ms. Hadas was Vice President and General Counsel at OvaScience, Inc., a biopharmaceutical company, in 2013. From 2011 to 2013, Ms. Hadas served as the Senior Vice President and General Counsel at Inspiration Biopharmaceuticals, Inc., a biopharmaceutical company that filed for protection under Chapter 11 of the U.S. Bankruptcy Code in October 2012, where she managed the successful sale of its hemophilia assets to Cangene Corporation and Baxter International in early 2013. From 2001 to 2011, Ms. Hadas worked at Genzyme Corporation, most recently as Senior Corporate Counsel. Prior to Genzyme, she was an associate at Foley Hoag representing biopharmaceutical companies and healthcare providers in a wide variety of matters. Ms. Hadas received a B.A. from the University of Michigan and a J.D. from Boston College Law School.

**Muneer A. Satter** has served as a member of our board of directors since 2012. Mr. Satter has been Chairman at Satter Investment Management LLC since 2012. He also manages the Satter Foundation. Prior to Satter Investment Management, Mr. Satter was a partner at Goldman Sachs where he spent 24 years in various roles, most recently as the Global Co-Head of the Principal Debt Group and Global Head of the Mezzanine Group in the Merchant Banking Division. He is Co-Chairman of the Board of Aerpio Therapeutics, Vital Therapies, Inc. and Linq3 Technologies LLC, and Chairman of the Board of Restorsea Holdings, LLC. He also serves as Vice Chairman of Goldman Sachs Foundation and GS Gives, is a director of The Nature Conservancy and World Business Chicago, is on the Board of Advisors of the American Enterprise Institute and is on the Board of Trustees of Northwestern University. Mr. Satter received a B.A. in Economics from Northwestern University, a J.D. from Harvard Law School, and an M.B.A. from Harvard Business School. We believe that Mr. Satter is qualified to serve on our board of directors due to his extensive investment experience.

**Campbell Murray, M.D.** has served as a member of our board of directors since 2008 and is our Co-Chairman. Dr. Murray has been a Managing Director of Novartis Venture Fund, since 2005. Prior to joining the fund, he worked at the Novartis Institutes for BioMedical Research as the Director of Special Projects. Dr. Murray currently serves on the board of directors of Aerpio Therapeutics, Alios BioPharm, Euthymics Biosciences, Galera Therapeutics, ImaginAb, Neurovance and Tokai Pharmaceuticals. Dr. Murray received a Bachelor of human biology from the University of Auckland Medical School, an M.B.A. from Harvard Business School, an M.P.P. from the John F. Kennedy School of Government, and an MBChB (M.D.) from the University of Auckland Medical School. We believe that Dr. Murray is qualified to serve on our board of directors due to his investment experience in the biotechnology sector.

**Jack Nielsen** has served as a member of our board of directors since 2013. Mr. Nielsen has worked within the Novo A/S organization and its venture activities since 2001 in several roles, most recently being employed as a Partner based in Copenhagen, Denmark. From 2006 to 2012, Mr. Nielsen was employed as a Partner at Novo Ventures (US) Inc. in San Francisco, where he established the office which provides certain consultancy services to Novo A/S. From 1990-2001, he held various positions in the Novo Nordisk business area which in 2000 became Novozymes A/S. Mr. Nielsen currently serves on the board of directors of Alios BioPharma Inc., Apollo Endosurgery Inc., BioClin Therapeutics Inc., ProteinSimple, Reata Pharmaceuticals Inc. and Tobira Therapeutics Inc. Previously, he was a board member of MediQuest Therapeutics Inc., NeoMend Inc. and Protein Forest Inc. Mr. Nielsen received a M.Sc. in Chemical Engineering from the Technical University in Denmark, and a Master in Management of Technology from Center for Technology, Economics and Management; Technical University of Denmark. We believe that Mr. Nielsen is qualified to serve on our board of directors due to his experience serving on boards in the biotechnology sector.

**Anupam Dalal, M.D.** has served as a member of our board of directors since 2008. Dr. Dalal has been a managing director at Kearny Venture Partners since 2008. Prior to working at Kearny Venture Partners, Dr. Dalal was a Principal at Flagship Ventures. Dr. Dalal currently serves on the board of directors of Aerpio Therapeutics. Dr. Dalal has served on the board of Resolvix Pharmaceuticals and Pervasis Therapeutics. Dr. Dalal received a B.A. in Economics from the University of California at Berkeley, an M.B.A. from Harvard Business School, and an M.D. from the University of California, San Francisco. Dr. Dalal was Resident in Surgery at Brigham and Women's Hospital / Harvard Medical School. We believe that Dr. Dalal is qualified to serve on our board of directors due to his investment and board experience in the biotechnology sector.

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**Giovanni Ferrara** has served as a member of our board of directors since 2013. Mr. Ferrara has been a Venture Partner at Novartis Venture Fund since 2011. Prior to joining Novartis, he spent three years as a consultant to west coast venture capital firms and as consulting Chief Business Officer to Sorbent Therapeutics, a biopharmaceutical company. Previously, he was Managing Director and General Partner at Burrill & Company, a venture fund, and began his venture capital career at GeneChem Management, where, in addition to investing, he also held operating positions in portfolio companies, including CEO of Targanta Therapeutics (then Phage Tech, Inc.). Mr. Ferrara received a B.Sc. in Human Genetics and Biology from the University of Toronto, and an M.B.A. and M.Sc. from McGill University. We believe that Mr. Ferrara is qualified to serve on our board of directors due to his management experience in the biotechnology sector.

**Kim Dueholm, Ph.D.** has served as a member of our board of directors since 2013. Mr. Dueholm has been employed as a partner at Novo A/S since 2000. Prior to joining Novo A/S, Mr. Dueholm spent five years with Novo Nordisk A/S in positions ranging from Patent Portfolio Analyst to Principal Scientific Analyst, from 1995 to 2000. He currently serves on the board of directors of ObsEva SA and Orphazyme ApS. Previously, he was a board member of Core A/S, F-star GmbH, NeuroKey A/S, Novoxel S.A., Nuevolution A/S and Symphogen A/S. He is also a member of the editorial board of Expert Opinion on Therapeutic Patents. Mr. Dueholm received an M.Sc. in Chemistry and Business Administration from Odense University, and a Ph.D. in organic chemistry from the University of Copenhagen. We believe that Dr. Dueholm is qualified to serve on our board of directors due to his management and director experience in the biotechnology sector.

**Duane Nash, M.D.** has served as a member of our board of directors since 2013. Dr. Nash has been the Executive Vice President since 2013 and Chief Business Officer since 2012 of Vital Therapies, Inc., a biopharmaceutical company. In 2012 and 2013, he also served as Medical Director. Dr. Nash joined Vital Therapies from Wedbush PacGrow Life Sciences, an investment bank, where he was employed from March 2009 to March 2012 serving most recently as Senior Vice President in Equity Research. Before that he was a research analyst at Pacific Growth Equities, an investment bank, from April 2008 through March 2009, which was subsequently acquired by Wedbush Securities, Inc. Dr. Nash also practiced as an attorney from November 2002 to February 2008, most recently at the law firm of Davis Polk, where he focused on intellectual property litigation and corporate matters. Dr. Nash currently serves on the board of directors of Aerpio Therapeutics Inc. Dr. Nash earned a B.A. in biology from Williams College, an M.D. from Dartmouth Medical School, a J.D. from the University of California, Berkeley, and an M.B.A. from the University of Oxford. Dr. Nash completed his internship in general surgery at the University of California at San Francisco. We believe that Dr. Nash is qualified to serve on our board of directors due to his management experience in the biotechnology sector.

**Michael S. Wyzga** has served as a member of our board of directors since February 2014. Mr. Wyzga has served as the President and Chief Executive Officer and a member of the board of directors of Radius Health, Inc., a biopharmaceutical company focused on developing new therapeutics for the treatment of osteoporosis and other women's health conditions, from December 2011 to November 2013. Prior to that, Mr. Wyzga served in various senior management positions at Genzyme Corporation, a global biotechnology company. Mr. Wyzga joined Genzyme in February 1998 and most recently served as Executive Vice President, Finance from May 2003 until November 2011 and as Chief Financial Officer from July 1999 until November 2011. Mr. Wyzga currently serves on the board of directors of Idenix Pharmaceuticals, Inc., a pharmaceutical company, and Oncomed Pharmaceuticals, Inc., a pharmaceutical company. Mr. Wyzga received a B.S. from Suffolk University and an M.B.A. from Providence College. We believe that Mr. Wyzga is qualified to serve on our board of directors due to his extensive executive and financial leadership.

In addition to the individual attributes of each of our directors listed above, we highly value the collective qualifications and experiences of our board members. We believe the collective viewpoints and perspectives of our directors results in a board that is dedicated to advancing the interests of our stockholders.

## **Board Composition and Election of Directors**

### ***Board Composition***

Our board of directors is currently comprised of nine members. However, Dr. Murray and Mr. Ferrara have notified the Company that they will resign from our board of directors immediately prior to the effectiveness of the registration statement. The members of our board of directors were elected in compliance with the provisions of the voting agreement among us and our major stockholders. The voting agreement will terminate upon the closing of this offering and we will have no further contractual obligations regarding the election of our directors. See “Certain Relationships and Related Party Transactions.” Our directors hold office until their successors have been elected and qualified or until their earlier death, resignation or removal.

Our amended and restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by resolution of our board of directors. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our amended and restated certificate of incorporation that will become effective upon the closing of this offering, our board of directors will be divided into three classes, class I, class II and class III, with members of each class serving staggered three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the class I directors will be Kim Dueholm and Duane Nash;
- the class II directors will be Anupam Dalal and Jack Nielsen; and
- the class III directors will be John P. Butler, Muneer A. Satter and Michael S. Wyzga.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

We have no formal policy regarding board diversity. Our priority in selection of board members is identification of members who will further the interests of our stockholders through his or her established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business and understanding of the competitive landscape.

### ***Director Independence***

Applicable NASDAQ rules require a majority of a listed company’s board of directors to be comprised of independent directors within one year of listing. In addition, the NASDAQ rules require that, subject to specified exceptions, each member of a listed company’s audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under applicable NASDAQ rules, a director will only qualify as an “independent director” if, in the opinion of the listed company’s board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

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In February 2014, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that Anupam Dalal, Kim Dueholm, Giovanni Ferrara, Campbell Murray, Duane Nash, Jack Nielsen, Muneer Satter, and Michael Wyzga are “independent directors” as defined under applicable NASDAQ rules. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Mr. Butler is not an independent director under these rules because he is an employee of Akebia. Please see the section of this prospectus titled “Certain Relationships and Related Party Transactions.”

There are no family relationships among any of our directors or executive officers.

### **Board Committees**

Effective upon the completion of this offering, our board of directors will have three standing committees: the audit committee, the compensation committee and the nominating and corporate governance committee. Our board of directors may establish other committees from time to time.

#### ***Audit Committee***

Effective upon the declaration of effectiveness of the registration statement of which this prospectus forms a part, our audit committee is expected to consist of Michael Wyzga, Kim Dueholm and Duane Nash, with Michael Wyzga serving as chairman of the committee. Our board of directors has determined that Michael Wyzga and Duane Nash meet the independence requirements of Rule 10A-3 under the Exchange Act and the applicable listing standards of NASDAQ. Our board of directors has determined that Michael Wyzga is an “audit committee financial expert” within the meaning of the SEC regulations and applicable listing standards of NASDAQ. The audit committee’s responsibilities upon completion of this offering will include:

- appointing, approving the compensation of, reviewing the performance of, and assessing the independence of our independent registered public accounting firm;
- pre-approving audit and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the internal audit plan with the independent registered public accounting firm and members of management responsible for preparing our financial statements;
- reviewing and discussing with management and the independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon its review and discussions with management and the independent registered public accounting firm, whether our audited financial statements shall be included in our Annual Report on Form 10-K;
- preparing the audit committee report required by the rules of the SEC to be included in our annual proxy statement;
- reviewing all related party transactions for potential conflict of interest situations and approving all such transactions; and

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- reviewing policies related to risk assessment and risk management; and establishing, maintaining and overseeing our Code of Business Conduct and Ethics.

### ***Compensation Committee***

Effective upon the declaration of effectiveness of the registration statement of which this prospectus forms a part, our compensation committee is expected to consist of Anupam Dalal, Jack Nielsen and Muneer Satter, with Anupam Dalal serving as chairman of the committee. Our board of directors has determined that each member of the compensation committee is “independent” as defined under the applicable listing standards of NASDAQ. The compensation committee’s responsibilities upon completion of this offering will include:

- annually reviewing and recommending for approval by the independent directors of the board individual and corporate goals and objectives relevant to the compensation of our executive officers;
- evaluating the performance of our executive officers in light of such individual and corporate goals and objectives and determining the compensation of our executive officers;
- appointing, compensating and overseeing the work of any compensation consultant, legal counsel or other advisor retained by the compensation committee;
- conducting the independence assessment outlined in NASDAQ rules with respect to any compensation consultant, legal counsel or other advisor retained by the compensation committee;
- annually reviewing and reassessing the adequacy of the committee charter in its compliance with the listing requirements of NASDAQ;
- overseeing and administering our compensation and similar plans;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and making recommendations to the board of directors with respect to director compensation;
- reviewing and approving stock option grants, and making recommendations to the board of directors with respect to stock option grants made to directors, executive officers, senior vice presidents or anyone reporting directly to our chief executive officer;
- reviewing and discussing with management the compensation discussion and analysis, if any, to be included in our annual proxy statement; and
- reviewing and discussing with the board of directors corporate succession plans for the chief executive officer and other senior management positions.

### ***Nominating and Corporate Governance Committee***

Effective upon the declaration of effectiveness of the registration statement of which this prospectus forms a part, our nominating and corporate governance committee is expected to consist of Jack Nielsen, Muneer Satter and Michael Wyzga, with Jack Nielsen serving as chairman of the committee. Our board of directors has determined that each member of the nominating and corporate governance committee is “independent” as defined under the applicable listing standards of NASDAQ. Following this offering, the nominating and corporate governance committee’s responsibilities will include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees; and
- developing and recommending to the board of directors a set of corporate governance principles.

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***Compensation Committee Interlocks and Insider Participation***

None of our executive officers serves as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any other entity that has one or more of its executive officers serving as a member of our board of directors or compensation committee. None of the members of our compensation committee has ever been employed by us. For a description of transactions between us and members of our compensation committee and affiliates of such members, please see the section of this prospectus titled “Certain Relationships and Related Party Transactions.”

***Code of Business Conduct and Ethics***

We have adopted a code of business conduct and ethics that applies to all of our employees, officers and directors, including those officers responsible for financial reporting. Upon the closing of this offering, our code of business conduct and ethics will be available on our website. We intend to disclose amendments to the code, or any waivers of its requirements, on our website as may be required by law or NASDAQ stock market listing standards.

## Executive Compensation

This section discusses the material elements of our executive compensation policies and decisions and important factors relevant to an analysis of these policies and decisions. It provides qualitative information regarding the manner and context in which compensation is awarded to and earned by our executive officers named in the “Summary Compensation Table” below and is intended to place in perspective the information presented in the following tables and the corresponding narrative.

### Overview

Historically, our executive compensation program has reflected our growth and corporate goals. To date, the compensation of our executive officers has consisted of a combination of base salary, annual cash bonus, long-term equity incentive compensation in the form of restricted stock and stock options and other employee benefits generally available to our employees. Certain of our executive officers are also entitled to certain compensation and benefits upon certain terminations of employment. Prior to March 3, 2014, these rights were determined pursuant to their employment agreements, as described below. Effective as of March 3, 2014, the rights of our executive officers to compensation and benefits upon a termination of employment will be determined pursuant to their executive severance agreements, as described below.

Our named executive officers for the year ended December 31, 2013 were as follows:

- John P. Butler, our President and Chief Executive Officer;
- Joseph Gardner, Ph.D., our former President and Chief Executive Officer;
- Robert Shalwitz, M.D., our Chief Medical Officer; and
- William Daly, our former Chief Business Officer.

John P. Butler was hired as our President and Chief Executive Officer in September 2013 and appointed as a member of our board of directors effective July 2013. In connection with Mr. Butler’s appointment, Dr. Gardner resigned as President and Chief Executive Officer and as a member of our board of directors, although he continues to serve as a consultant to the Company.

We and William Daly mutually agreed to terminate Mr. Daly’s employment effective as of February 7, 2014, although he continues to serve as a consultant to the Company, all as described in more detail below under “Employment Agreements with Our Named Executive Officers.”

### Elements of Executive Compensation

*Base Salaries.* Base salaries for our named executive officers are determined annually by our compensation committee, subject to review and approval by our board of directors, based on the scope of each officer’s responsibilities along with his respective experience and contributions to the company during the prior year period. When reviewing base salaries, our compensation committee takes factors into account such as each officer’s experience and individual performance, the company’s performance as a whole, data from surveys of compensation paid by comparable companies, and general industry conditions, but does not assign any specific weighting to any factor.

*Annual Cash Bonuses.* Our annual cash bonus program promotes and rewards our executives for the achievement of key strategic and business goals. The bonus plan period has historically covered the twelve consecutive month period ending each June 30. For 2013, we decided to change the bonus plan period to a calendar year period ending each December 31. As a result, the 2013 bonus plan period covers the 18-month period beginning on July 1, 2012 and ending on December 31, 2013. For the 2013 bonus plan period, the target annual bonus as a percentage of base salary (as determined based on the salary earned throughout the bonus plan period) for each of Mr. Butler, Dr. Shalwitz, and Mr. Daly was 30%, 20% and 20%, respectively. At the beginning of the 2013 bonus plan period, our compensation committee established corporate performance goals, each having a designated weighting, that related to key development, strategic and financial goals of the company. At the end of the 2013 bonus plan period, our compensation committee met and evaluated the performance of the company against the specified performance goals. For Mr. Daly and Dr. Shalwitz, the payout is dependent in part upon the

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achievement of specified performance goals for Aerpio. The portion of the payout that is dependent on those goals is determined by reference to the amount of time spent by the executive officer on Aerpio matters (5% for Dr. Shalwitz and 30% for Mr. Daly). Based on its evaluation, the compensation committee recommended and the board of directors approved, payment of cash bonuses for the 2013 bonus plan period of: \$37,188 for Mr. Butler (which represented 100% of his target bonus, as prorated to reflect his commencement of employment in September 2013), \$59,863 for Dr. Shalwitz (which represented 72% of his target bonus), and \$40,165 to Mr. Daly (which represented 50% of his target bonus). Due to other benefits provided to Dr. Gardner in connection with his Separation Agreement, Dr. Gardner did not receive a cash bonus for the 2013 bonus plan period.

**Equity Awards.** Our named executive officers participate in our Akebia Therapeutics, Inc. 2008 Equity Incentive Plan, or the 2008 Equity Incentive Plan. During fiscal 2013, Mr. Butler received a grant of stock options, Dr. Gardner and Dr. Shalwitz received a grant of restricted stock and Mr. Daly received grants of stock options and restricted stock. These stock option and restricted stock grants are subject to time-based vesting conditions and generally vest, subject to continued employment, as to 25% of the shares subject to the award after one year and thereafter continue to vest in quarterly installments over the following three years. These equity awards serve to align the interests of our named executive officers with our shareholders. They also encourage retention through the use of time-based vesting. For more information regarding the awards granted under the 2008 Equity Incentive Plan, please refer to “Equity Incentive Plans—2008 Equity Incentive Plan” below.

**Benefits.** Our named executive officers are eligible for benefits, such as participation in our 401(k) plan and basic health and welfare benefit coverage, that are generally available to all of our employees.

### Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by or paid to each of our named executive officers during the fiscal years ending December 31, 2013 and 2012.

Summary Compensation Table

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)<sup>(1)</sup></u>	<u>Stock Awards (\$)<sup>(2)</sup></u>	<u>Option Awards (\$)<sup>(3)</sup></u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
John P. Butler <i>President and Chief Executive Officer</i>	2013	124,802 <sup>(5)</sup>	37,188	—	2,126,887	40 <sup>(4)</sup>	2,288,917
Joseph Gardner, Ph.D. <i>Former President and Chief Executive Officer</i>	2013	203,472 <sup>(8)</sup>	—	1,068,100 <sup>(12)</sup>	50,317 <sup>(13)</sup>	28,530 <sup>(6)</sup>	1,350,419
	2012	275,000	36,438	—	44,546	251 <sup>(4)</sup>	356,235
Robert Shalwitz, M.D. <i>Chief Medical Officer</i>	2013	294,140 <sup>(9)</sup>	59,863	943,983	—	24,982 <sup>(7)</sup>	1,322,968
	2012	269,280	31,680	—	6,126	455 <sup>(4)</sup>	307,541
William Daly <i>Senior Vice President, Business Development</i>	2013	289,583 <sup>(10)</sup>	40,165	47,990	523,024	697 <sup>(4)</sup>	901,459
	2012	259,375 <sup>(11)</sup>	20,625	57,089	—	455 <sup>(4)</sup>	337,544

- (1) Amounts for 2013 represent cash bonuses earned for the 18-month bonus plan period from July 1, 2012 to December 31, 2013. Amounts for 2012 represent cash bonuses earned for the 12-month bonus plan period from July 1, 2011 to June 30, 2012.
- (2) The amount reported in the Stock Awards column granted to our named executive officers represents the retrospective fair value of the stock awards as of the grant date in accordance with ASC, Topic 718.
- (3) The amounts reported in the Option Awards column granted to our named executive officers represent the retrospective fair value of the stock options as of the grant date as computed in accordance with Accounting Standards Codification, or ASC, Topic 718, not including any estimates of forfeitures. The assumptions used in calculating the grant date fair value of the stock options reported in the Option awards column are set forth in Note 12 to our consolidated



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financial statements included elsewhere in this prospectus. Note that the amounts reported in this column reflect the accounting cost for these stock options, and do not correspond to the actual economic value that may be received by the named executive officers from the options.

- (4) Amounts represent the dollar value of life insurance premiums paid by the company on behalf of the named executive officer.
- (5) Mr. Butler joined us in September 2013. Mr. Butler's annual base salary in 2013 was \$425,000. The amounts in the table above reflect his partial year of service in 2013.
- (6) Amounts include: (i) \$522 for the dollar value of life insurance premiums paid by the company and (ii) forgiveness of principal on a portion of promissory notes to the company in the amount of \$28,008. See Note 12 under *2013 Outstanding Equity Awards at Fiscal Year-End*.
- (7) Amounts include: (i) \$696 for the dollar value of life insurance premiums paid by the company and (ii) forgiveness of principal on a portion of promissory notes to the company in the amount of \$24,286. See Note 12 under *2013 Outstanding Equity Awards at Fiscal Year-End*.
- (8) Dr. Gardner's annual base salary was \$275,000 from January 2013 through July 2013, and was \$350,000 beginning August 1, 2013. Dr. Gardner resigned as President and Chief Executive Officer and as a member of our board of directors on September 15, 2013. The amounts in the table above reflect his partial year of service in 2013.
- (9) Dr. Shalwitz's annual base salary was \$269,280 from January 2013 through July 2013, and was \$330,000 beginning August 1, 2013.
- (10) Mr. Daly's annual base salary was \$275,000 from January 2013 through July 2013, and was \$310,000 beginning August 1, 2013. The Company and William Daly mutually agreed to terminate Mr. Daly's employment effective as of February 7, 2014, although he continues to serve as a consultant to the Company.
- (11) Mr. Daly joined us in January 2012. Mr. Daly's annual base salary in 2012 was \$275,000. The amounts in the table above reflect his partial year of service in 2012.
- (12) Amount represents the fair value of the following awards at the grant dates: (1) 21,153 shares granted pursuant to the separation agreement described in "Employment Agreements with Our Named Executive Officers" below and 60,430 shares granted following Mr. Gardner's resignation, in each case in consideration of his prior service as our President and Chief Executive Officer and (2) 19,398 shares granted pursuant to the consulting agreement described in "Employment Agreements with Our Named Executive Officers" below, as compensation for services to be performed in his new role as consultant to the Company. The amount also includes \$15,100 associated with the accelerated vesting of restricted stock pursuant to Dr. Gardner's Separation Agreement.
- (13) Amount represents the value associated with accelerated vesting of stock options pursuant to Dr. Gardner's Separation Agreement.

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**2013 Outstanding Equity Awards at Fiscal Year-End**

The following table sets forth information concerning outstanding equity awards for each of our named executive officers at December 31, 2013:

<u>Name and Principal Position</u>	<u>Stock Options</u>				<u>Stock Awards<sup>(11)</sup></u>	
	<u>Number of Securities Underlying Unexercised Options (#) Exercisable</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>	<u>Number of Shares or Units of Stock That Have Not Vested (#)</u>	<u>Market Value of Shares of Stock That Have Not Vested (\$)<sup>(10)</sup></u>
John P. Butler . . . . . <i>President and Chief Executive Officer</i>	—	350,000 <sup>(1)</sup>	\$ 0.82	9/16/2023	—	—
Joseph Gardner, Ph.D. <i>Former President and Chief Executive Officer</i>	—	— <sup>(2)</sup>	—	—	— <sup>(2)</sup>	—
Robert Shalwitz, M.D. <i>Chief Medical Officer</i>	38,029	—	\$ 1.50	6/1/2018	—	—
	14,864	2,469 <sup>(3)</sup>	\$ 1.50	7/28/2020	7,473 <sup>(6)</sup>	97,074
	5,402	5,270 <sup>(4)</sup>	\$ 1.50	1/12/2022	72,670 <sup>(7)</sup>	943,983
William Daly <i>Senior Vice President, Business Development</i>	—	—	—	—	15,650 <sup>(8)</sup>	203,924
	—	51,698 <sup>(5)</sup>	\$ 6.60	12/23/2023	30,763 <sup>(9)</sup>	399,611

- (1) Represents options to purchase shares of our common stock granted on September 16, 2013. The remaining unvested shares will vest as follows: 25% vest on September 16, 2014, with the remainder of the shares vesting in equal monthly installments over the following three years through September 16, 2017. Vesting of all unvested options shall accelerate in connection with an acquisition event pursuant to the terms of the option agreement.
- (2) In connection with Dr. Gardner’s resignation as President and Chief Executive Officer and as a member of our board of directors, all of Dr. Gardner’s outstanding equity awards were accelerated and became fully vested as of September 15, 2013 pursuant to his Separation Agreement. Following his separation, 78,203 options with a weighted-average exercise price of \$1.50 per share expired unexercised.
- (3) Represents options to purchase shares of our common stock granted on July 28, 2010. The remainder of these options vests in equal monthly installments through July 28, 2014. Vesting of all unvested options shall accelerate in connection with an acquisition event pursuant to the terms of the option agreement.
- (4) Represents options to purchase shares of our common stock granted on January 12, 2012. The remainder of these options vests in equal monthly installments through December 23, 2015. Pursuant to the terms of the award agreement, vesting of all unvested options shall accelerate in connection with an acquisition, in the event the option is not assumed by the acquirer, or in the event the option is assumed by the acquirer and the executive’s employment is terminated or materially diminished within the following 12 months.
- (5) Represents options to purchase shares of our common stock granted on December 23, 2013. Prior to cancellation, the remaining unvested shares were scheduled to vest as follows: 25% vest on April 1, 2014, with the remainder of the shares vesting in equal monthly installments over the following three years through April 1, 2017, with vesting of all unvested options accelerating in connection with an acquisition event pursuant to the terms of the option agreement; provided that no shares would vest prior to the occurrence of a liquidity event. All of these options were cancelled pursuant to the Separation Agreement between us and Mr. Daly, as described below.
- (6) Under the terms of the June 15, 2011 restricted stock agreement, the remaining unvested shares will vest in equal monthly installments through April 6, 2015. Vesting of all restricted shares shall accelerate in connection with an acquisition event pursuant to the terms of the restricted stock agreement.
- (7) Under the terms of the December 23, 2013 restricted stock agreement, the remaining unvested shares will vest as follows: 25% vest on December 23, 2014, with the remainder of the shares

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vesting in equal quarterly installments over the following three years through December 23, 2017; provided that no shares or restricted stock would vest prior to the occurrence of a liquidity event. Vesting of all restricted shares shall accelerate in connection with an acquisition event pursuant to the terms of the restricted stock agreement.

- (8) Under the terms of the February 21, 2012 restricted stock agreement: 25% vested on January 22, 2013, with the remainder of the unvested shares vesting in equal monthly installments over the following three years through January 22, 2016. Pursuant to the terms of the award agreement, vesting of all unvested shares shall accelerate in connection with an acquisition, in the event the award is not assumed by the acquirer, or in the event the award is assumed by the acquirer and the executive's employment is terminated or materially diminished within the following 12 months. The vesting schedule for these shares was revised pursuant to the Separation Agreement and the Consulting Agreement between us and Mr. Daly, as described below.
- (9) Prior to cancellation, under the terms of the April 1, 2013 restricted stock agreement, the remaining unvested shares were scheduled to vest as follows: 25% vest on April 1, 2014, with the remainder of the shares vesting in equal monthly installments over the following three years through April 1, 2017 and vesting of all unvested shares shall accelerate in connection with an acquisition, in the event the award is not assumed by the acquirer, or in the event the award is assumed by the acquirer and the executive's employment is terminated or materially diminished within the following 12 months. All of these shares of restricted stock were cancelled pursuant to the Separation Agreement between us and Mr. Daly, as described below.
- (10) The value of the unvested restricted stock was \$12.99 per share based on an independent, third-party appraisal of our common stock as of December 31, 2013.
- (11) The restricted stock awards for Dr. Gardner and Dr. Shalwitz were purchased using promissory notes issued by the executives to the Company (the "Promissory Notes") for \$140,884 and \$110,692, respectively. The Promissory Notes were amended in 2013 to forgive a portion of the principal owed and to reduce the interest rate from 6% to 3% per annum. The aggregate balance of the outstanding Promissory Notes at December 31, 2013 was \$112,831 for Dr. Gardner and \$86,406 for Dr. Shalwitz. The Promissory Notes are repayable at the earlier of (a) an initial public offering; (b) the sale of the company or substantially all of its assets; (c) the termination of the employee; or (d) five years from origination. Dr. Shalwitz's note, including accrued interest in the aggregate amount of \$88,072, was forgiven on January 30, 2014.

### **Retention Bonuses**

We have established a retention bonus program in which our named executive officers participate. This program provides that if the named executive officers remain employed with us through a "Sale of the Company" (as defined in the Third Amended and Restated Voting Agreement), they will be paid a bonus in the same form and manner as payments made to holders of our Series C Preferred Stock in connection with the "Sale of the Company". Each participant in the program is entitled to a designated percentage of a bonus pool. The designated percentages have not yet been determined and no awards have been made pursuant to this program. The size of the bonus pool is based on (i) the percentage of our fully-diluted equity that is represented by vested awards under our 2008 Equity Incentive Plan immediately prior to a Sale of the Company (up to a maximum of 12.5%) multiplied by (ii) fifty percent of the Applicable Accrued Value (as defined in our eighth amended and restated certificate of incorporation) of our Series C Preferred Stock. We do not expect to maintain the retention bonus program following the consummation of this offering.

### **Retirement Benefits**

We offer a tax-qualified retirement plan, or 401(k) plan, to eligible employees, including our named executive officers. In accordance with this plan, all eligible employees may contribute a percentage of compensation up to a maximum of the statutory limits per year. Company contributions are discretionary and no contributions were made during 2013 or 2012.

### **Employment Agreements with Our Named Executive Officers**

We have entered into an employment agreement with each of our named executive officers, except for Mr. Daly, with whom we entered into an offer letter at the time he commenced employment with us. Each of these employment agreements and offer letter provides for "at will" employment, meaning that either we or the named executive officer may terminate our employment relationship at any time without cause.

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*John P. Butler.* On September 16, 2013, we entered into an executive employment agreement with Mr. Butler for the position of President and Chief Executive Officer. The executive employment agreement continues until we or Mr. Butler terminates the agreement in accordance with its terms. Mr. Butler currently receives a base salary of \$425,000, which is subject to review by our Board of Directors from time to time, and at least every 12 months. Mr. Butler is also eligible to receive an annual performance-based cash bonus of up to 30% of Mr. Butler's base salary, determined by our board of directors and based upon the company's performance and Mr. Butler's performance against objectives established by our board of directors. Mr. Butler is entitled to four weeks of vacation, as well as holidays and sick leave, and (subject to eligibility criteria under the applicable plan) the right to participate in any profit sharing plan, retirement plan, 401(k) plan, group medical plan, group dental plan, and/or other health or insurance plan maintained by us for our senior executives generally and, if applicable, their family members. Mr. Butler is also entitled to reimbursement of all reasonable and necessary business and travel expenses incurred in connection with the performance of his duties.

*Dr. Joseph Gardner.* On May 2, 2007, we entered into an executive employment agreement with Dr. Gardner for the position of President and CEO; this agreement was subsequently amended on April 6, 2011. Dr. Gardner's base salary during 2013 was \$350,000, which was subject to review by our Board of Directors from time to time during his employment, and at least every 12 months. Dr. Gardner was also eligible to participate in discretionary bonus programs on both a quarterly and annual basis, as determined by our Board of Directors, in its sole discretion; provided; that Dr. Gardner was not entitled to payment of any such bonus unless he remained actively employed through the end of the applicable calendar quarter or year. Dr. Gardner was entitled to four weeks of vacation, as well as holidays and sick leave, and (subject to eligibility criteria under the applicable plan) the right to participate in any profit sharing plan, retirement plan, 401(k) plan, group medical plan, group dental plan, and/or other health or insurance plan maintained by us for our senior executives generally and, if applicable, their family members. Dr. Gardner was also entitled to reimbursement of all reasonable and necessary business and travel expenses incurred in connection with the performance of his duties. Dr. Gardner resigned as President and CEO in September 2013. He continues to serve as a consultant. Although Dr. Gardner was not entitled to any severance under his employment agreement upon his termination of employment, we entered into a separation agreement with him that provided for the accelerated vesting of all his then unvested options and restricted stock. The separation agreement also provided Dr. Gardner with an award of 21,153 shares of unrestricted common stock, without consideration therefor, and stated that Dr. Gardner would participate in the retention bonuses described above. The separation agreement also contained a release of claims in favor of the company. Concurrent with the separation agreement, we entered into a standard consulting agreement with Dr. Gardner pursuant to which we granted him 19,398 unrestricted shares of our common stock.

*Dr. Robert Shalwitz.* On April 6, 2011, we entered into an executive employment agreement with Dr. Shalwitz for the position of Chief Medical Officer and Vice President. Dr. Shalwitz currently receives a base salary of \$330,000, which is subject to review by our Board of Directors from time to time, and at least every 12 months. Dr. Shalwitz is also eligible to participate in all bonus or similar incentive plans adopted by our Board of Directors including, without limitation, an incentive compensation plan with a yearly performance-based cash bonus of up to 20% of Dr. Shalwitz's base salary. Dr. Shalwitz is entitled to four weeks of vacation, as well as holidays and sick leave, and (subject to eligibility criteria under the applicable plan) the right to participate in any profit sharing plan, retirement plan, 401(k) plan, group medical plan, group dental plan, and/or other health or insurance plan maintained by us for our senior executives generally and, if applicable, their family members. We pay 100% of Dr. Shalwitz's premiums under our medical and dental plans and 50% of the premiums associated with the coverage of his spouses/dependents under those same plans. Dr. Shalwitz is also entitled to reimbursement of all reasonable and necessary business and travel expenses incurred in connection with the performance of his duties.

*Mr. William Daly.* On January 2, 2012, we entered into an offer letter with Mr. Daly for the position of Senior Vice President of Business Development. Under the offer letter, Mr. Daly received an annual base salary of \$310,000 and was eligible for performance-based cash bonuses of up to a maximum of 20% of base salary per year. Mr. Daly's offer letter also entitled him to an initial grant of restricted stock under our 2008 Equity Incentive Plan, subject to approval by our board of directors. For more information about the restricted stock

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grant made to Mr. Daly upon the commencement of his employment in 2012, please see the 2013 Outstanding Equity Awards at Fiscal Year-End table above. Mr. Daly's base salary and incentive compensation were subject to review on an annual basis. Mr. Daly was entitled to participate in all benefit plans as may have been offered by us from time to time during his employment. We and Mr. Daly mutually agreed to terminate Mr. Daly's employment effective as of February 7, 2014. In connection with his resignation, we and Mr. Daly entered into a Separation Agreement and Consulting Agreement. Under the Separation Agreement, Mr. Daly is entitled to twelve months of salary continuation (in an aggregate amount of \$310,000) and payment of a portion of his COBRA premiums for a maximum of twelve months (on the same basis as the medical insurance premium paid by us during his employment), as well as a reimbursement of up to \$5,000 for legal fees incurred. In addition, the Separation Agreement provides for the following treatment of Mr. Daly's outstanding equity incentive awards: (i) the cancellation, without consideration therefor, of 51,698 stock options granted on December 23, 2013 and 30,763 shares of restricted stock granted on April 1, 2013 and (ii) the continued vesting of 30,047 shares of restricted stock granted on February 21, 2012 during the twelve month period following his separation, with any remaining unvested portion of this restricted stock award vesting on the last day of such twelve month period or, if earlier, upon a change of control of the company (as defined in the consulting agreement) or the termination of the Consulting Agreement by us without cause (as defined in the consulting agreement). Our obligation to provide Mr. Daly with these severance benefits, including the continued vesting of his February 21, 2012 restricted stock award, is conditioned on his continued compliance with the terms of the Consulting Agreement and the Separation Agreement, including the restrictive covenants described below. The Separation Agreement also includes a general release from any liability related to the employment and termination of Mr. Daly.

Under Mr. Daly's Consulting Agreement, he will continue, for a twelve-month period following February 7, 2014, to advise us with respect to, among other things, our business development activities and intellectual property portfolio. As consideration for the performance of these services and his continuing obligation to abide by certain restrictive covenants related to non-competition, non-solicitation and confidentiality, the Consulting Agreement provides Mr. Daly with a grant of 32,000 shares of restricted stock and a \$150,000 payment to partially offset a valid Code section 83(b) election. Half of this restricted stock grant vests on the six-month anniversary of the Consulting Agreement, with the remainder vesting on the expiration of the Consulting Agreement or, if earlier, upon a change of control of the company (as defined in the Consulting Agreement) or the termination of the consulting agreement by us without cause (as defined in the Consulting Agreement). If Mr. Daly terminates the consulting agreement for convenience or we terminate it for cause (as defined in the Consulting Agreement), then the vesting of all equity (i.e., the February 21, 2012 restricted stock award and the 32,000 shares of restricted stock provided in consideration for his consulting services) and the payment of all severance and benefits under the Consulting Agreement and the Separation Agreement shall cease.

### ***Involuntary Termination of Employment and Change of Control***

Pursuant to their employment agreements, Mr. Butler, Dr. Gardner and Dr. Shalwitz are eligible to receive certain payments and benefits in the event that the executive's employment is terminated by us without "cause" (as defined in the applicable employment agreement), the executive terminates his employment with us for "good reason" (as defined in the applicable employment agreement) or, with respect to Dr. Gardner and Dr. Shalwitz (but not Mr. Butler), the executive is terminated in connection with or within six months following a "change of control" (as defined in the applicable employment agreement). As described below, effective as of March 3, 2014, we entered into a new executive severance agreement with each of Mr. Butler and Dr. Shalwitz. These executive severance agreements supersede the provisions regarding post-separation severance and benefits and equity acceleration in connection with a change of control included in Mr. Butler's and Dr. Shalwitz's employment agreements, which otherwise remain in effect in accordance with their terms. From and after March 3, 2014, the rights of Mr. Butler and Dr. Shalwitz to any payments or benefits following a termination of employment will be determined under the executive severance agreements described below.

Under their employment agreements, the severance payable to Dr. Gardner and Dr. Shalwitz in each applicable situation, which is subject in all cases to the execution of a release of claims in our favor and continued compliance with a set of restrictive covenants prohibiting certain competitive behaviors by the executive within

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the one-year period immediately following his termination of employment, is equal to six months of salary continuation, the Company's payment of the executive's COBRA premiums for a maximum of six months, and six months of participation in our group insurance benefits (other than health insurance) in which the executive participated immediately prior to termination. As noted above, Dr. Gardner resigned as President and CEO on September 15, 2013. Except as described above, no severance was or is payable to Dr. Gardner under his employment agreement in connection with this termination of employment.

Under his employment agreement, the severance payable to Mr. Butler in each applicable situation, which is subject in all cases to the execution of a release of claims in our favor and continued compliance with a set of restrictive covenants prohibiting certain competitive behaviors by Mr. Butler within the one-year period immediately following his termination of employment, is equal to twelve months of salary continuation and the Company's payment of Mr. Butler's COBRA premiums for a maximum of twelve months. In addition, Mr. Butler is entitled to receive a pro-rata portion of his annual target bonus for the calendar year in which his termination of employment occurs.

### ***Executive Severance Agreements***

On February 28, 2014, our board of directors adopted a form of executive severance agreement, or ESA, under which our officers, including our named executive officers, are eligible to receive certain payments and benefits in the event that the executive's employment with us is terminated without "cause," the executive terminates his or her employment with us for "good reason," or the executive is terminated in connection with or within 12 months after a "change in control" (each as defined in the ESA). The ESAs also provide for accelerated vesting of outstanding and unvested equity awards upon a "change in control" (as defined in the ESA). Effective as of March 14, 2014, we entered into ESAs with Mr. Butler and Dr. Shalwitz. The terms of the ESAs with Mr. Butler and Dr. Shalwitz supersede the terms of all existing agreements between us and such executives regarding post-separation severance and benefits and equity acceleration in connection with a change of control, including any such terms in the severance provisions of each of their employment agreements, as described above, and any such terms in any outstanding equity award. All other terms of any existing agreement between such executives and us, such as the terms of their existing employment agreements related to compensation and benefits during employment, will otherwise remain in full force and effect in accordance with the terms of such existing agreements.

***Termination of Employment without Cause or for Good Reason.*** Under the ESA, if Mr. Butler's or Dr. Shalwitz's employment is terminated by us without "cause" or the executive terminates his employment for "good reason" (each as defined in the ESA), other than following a change in control as described below, the executive will be entitled to receive, in addition to any amounts earned or accrued but unpaid as of the date of termination, 12 months of salary continuation and up to 12 months of reimbursement of a portion of the executive's health and dental COBRA premiums to the same extent as if the executive remained employed. In addition, the executive's unvested equity and equity-based awards will remain outstanding and continue to vest in accordance with their terms during the executive's severance period, as if he had remained employed during that time.

***Termination of Employment without Cause or for Good Reason Following a Change in Control.*** If, within 12 months following a "change in control" (as defined in the ESA), Mr. Butler's or Dr. Shalwitz's employment is terminated by us without "cause" or the executive terminates his employment for "good reason" (each as defined in the ESA), the executive will be entitled to receive, in addition to any amounts earned or accrued but unpaid as of the date of termination, 12 months of salary continuation, up to 12 months' of reimbursement of a portion of the executive's health and dental COBRA premiums to the same extent as if the executive remained employed, and an amount equal to fifty percent (50%) of the executive's annual target bonus for the year of termination, prorated based on the number of months the executive was employed during the year prior to termination. In addition, the executive's unvested equity and equity-based awards will remain outstanding and continue to vest in accordance with their terms during the executive's severance period, as if he had remained employed during that time.

***Conditions to the Receipt of Severance Benefits.*** The severance payments and benefits described above are conditioned upon Mr. Butler's or Dr. Shalwitz's execution of a general release of claims in our favor and continued compliance with a set of restrictive covenants prohibiting certain competitive behaviors following

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termination and a prohibition on making certain statements that are disparaging about or adverse to our business interests or that are otherwise intended to harm our reputation for at least one year following termination. In addition, we may terminate severance payments to either Mr. Butler or Dr. Shalwitz if, within one year following a termination without cause, we determine that the Company had the right to terminate his employment for cause.

**Accelerated Vesting of Equity upon a Change in Control.** Under the ESA, 100% of each of Mr. Butler's and Dr. Shalwitz's outstanding and unvested equity and equity-based awards will become immediately vested upon a "change in control," (as defined in the ESA) irrespective of whether his employment terminates in connection with the change in control.

**Other Termination of Employment.** If Mr. Butler's or Dr. Shalwitz's employment is terminated for any reason other than by us without cause or by the executive for good reason (including by reason of death or disability), the executive will only be entitled to receive any amounts earned or accrued but unpaid as of the date of termination in accordance with our normal policies and practices, including any salary, bonus or incentive compensation with respect to the calendar year prior to the year of termination, business expenses incurred in the performance of the executive's duties, and vacation pay.

**280G Cutback.** All payments to Mr. Butler or Dr. Shalwitz under the ESA, including, without limitation, the payment of severance benefits or the accelerated vesting of equity, will be reduced or adjusted to avoid triggering the excise tax imposed by Section 4999 of the Code, if such adjustment would result in the provision of a greater total benefit, on a net after-tax basis (after taking into account taking any applicable federal, state and local income taxes and the excise tax imposed by Section 4999), to the executive.

**Termination of ESA.** Each of Mr. Butler's and Dr. Shalwitz's ESA will terminate immediately upon the mutual agreement of the parties to such ESA, the executive's termination for cause or death, or the executive's disability (defined as the executive's inability by reason of physical or mental impairment to perform his job duties for a period exceeding twelve (12) consecutive weeks).

### **Equity Incentive Plans**

All outstanding equity-based awards have been granted under our 2008 Equity Incentive Plan, as described below. Following this offering, all equity-based awards will be granted under the 2014 Incentive Plan described below.

#### **2008 Equity Incentive Plan**

Our Board of Directors and shareholders originally approved the 2008 Equity Incentive Plan, effective as of April 4, 2008. The following summary describes the material terms of the 2008 Equity Incentive Plan, as most recently amended effective August 3, 2013. This summary of the 2008 Equity Incentive Plan is not a complete description of all provisions of the 2008 Equity Incentive Plan and is qualified in its entirety by reference to the 2008 Equity Incentive Plan, which will be filed as an exhibit to the registration statement of which this prospectus is a part.

**Administration.** The 2008 Equity Incentive Plan is administered by our Board of Directors. Our Board of Directors has the authority to, among other things, determine to which of the eligible persons under the plan awards will be granted, determine the type of award to grant, approve forms of award agreements, determine the number of shares subject to, and the terms and conditions of, an award, construe and interpret the plan and awards and establish, amend and revoke rules and regulations for the administration of the plan and awards, correct defects in the plan and awards and generally, to exercise such powers and perform such acts as it deems to be necessary or expedient to make the plan fully effective. Our Board of Directors' determinations under the 2008 Equity Incentive Plan are final and conclusive.

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*Eligibility.* Our employees, directors, and consultants are eligible to participate in the 2008 Equity Incentive Plan. Eligibility for stock options intended to be incentive stock options, or ISOs, as defined in Section 422 of the Code, is limited to our employees.

*Authorized Shares.* Subject to adjustment, as described below, as of January 24, 2014, the number of shares of our common stock reserved for future issuance under the 2008 Equity Incentive Plan is 88,633 shares. The shares of our common stock to be issued under the 2008 Equity Incentive Plan may be authorized but unissued shares of our common stock or previously issued shares of our common stock acquired by us. Any shares of our common stock underlying awards that are settled in cash, forfeited, repurchased or otherwise reacquired by us, expired, cancelled or become unexercisable without having been exercised and any shares of our common stock used to satisfy an applicable tax withholding obligation will again be available for issuance under the 2008 Equity Incentive Plan.

*Types of Awards.* The 2008 Equity Incentive Plan provides for awards of stock options, restricted stock and unrestricted stock.

- *Stock options.* The exercise price of an ISO may not be less than the fair market value (or, in the case of an ISO granted to a ten percent shareholder, 110% of the fair market value) of shares of our common stock on the date of grant. The exercise price of each non-statutory stock option (or NSO) is the exercise price determined by our Board of Directors. The Board of Directors has set the exercise price of all NSOs granted under the 2008 Equity Incentive Plan at the fair market value of shares of our common stock as of the actual date of grant. Our Board of Directors will determine the time or times at which stock options become exercisable and the terms on which such awards remain exercisable.
- *Restricted stock and stock bonuses.* A restricted stock award is an award of shares of our common stock subject to forfeiture restrictions. A stock bonus is not subject to such restrictions. Our Board of Directors will determine the time or times at which any applicable vesting conditions and/or repurchase rights on restricted and unrestricted stock awards will lapse.

*Vesting; Termination of Employment or Service.* Our Board of Directors has the authority to determine the vesting schedule applicable to each award, and to accelerate the vesting or exercisability of any award. In the case of stock options, our Board of Directors may provide for early exercise of unvested options, with the stock received upon such exercise being subject to vesting. Our Board of Directors will determine the effect of termination of employment or service on an award. Unless otherwise provided in an award agreement, upon a termination of a participant's employment or service, all unvested stock options held by the participant on the date notice of termination is given to the optionee will terminate and all other unvested awards will be forfeited and all vested stock options then held by the participant will remain outstanding for one month following the provision of notice of such termination, or, in the case of death or disability, one year following the date of death or the provision of notice of termination by reason of disability or, in each case, until the applicable expiration date, if earlier. All stock options held by a participant immediately prior to the participant's termination of employment or service will immediately terminate if such termination is for cause, as defined in the 2008 Equity Incentive Plan. Unless otherwise provided by our Board of Directors, a stock bonus or restricted stock award shall cease vesting upon a participant's termination of employment or service (and, if applicable, the right to acquire any stock purchasable under such award will cease).

*Non-Transferability of Awards.* Awards under the 2008 Equity Incentive Plan may not be transferred other than by will or by the laws of descent and distribution, unless, for awards other than ISOs, otherwise provided in an award agreement (and subject, in the case of restricted stock and unrestricted stock awards to any applicable buy-sell or similar arrangements).

*280G cutback.* If any payment or right accruing to an individual under the 2008 Equity Incentive Plan would (alone or together with any other payment or right) constitute a "parachute payment" for purposes of Section 280G of the Code, then such payment or right under the 2008 Equity Incentive Plan will be reduced to



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the largest amount or greatest right that will result in no portion of such payment or right being a “parachute payment”. This provision will only apply if the individual would receive less on an after tax basis if he or she did not have his or her payment or right under the 2008 Equity Incentive Plan so reduced.

**Certain Transactions; Certain Adjustments.** In the event of a merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by the corporation, the Board of Directors will appropriately adjust the maximum number of shares that can be issued under the 2008 Equity Incentive Plan, as well as all outstanding awards, except that no adjustment will be made if it would cause an equity award intended to be an ISO to fail to so qualify.

In the event of a deemed liquidity event (as defined in our certificate of incorporation), our Board of Directors may provide for substitute awards or such alternative consideration, including cash, as it deems equitable in the situation. In the event that our Board of Directors does not provide for such substitution or consideration in connection with a covered transaction, except as otherwise provided in an award agreement, all unexercised options will terminate automatically and, in the case of outstanding unvested restricted stock or stock bonus awards, will be forfeited automatically (in exchange for an amount equal to the original purchase price, if any) upon the consummation of such covered transaction. No additional awards may be made under the 2008 Equity Incentive Plan following a covered transaction.

**Amendment; Termination.** Our Board of Directors may, in its discretion, amend the 2008 Equity Incentive Plan or suspend or terminate the 2008 Equity Incentive Plan at any time, except that our Board of Directors may not reduce any outstanding award without the participant’s written consent. Shareholder approval will be required for any amendment to the 2008 Equity Incentive Plan to the extent such approval is required by law. Unless earlier terminated by our Board of Directors, the 2008 Equity Incentive Plan will terminate by its terms on April 3, 2018.

### **2014 Incentive Plan**

On February 28, 2014, our board of directors adopted the Akebia Therapeutics, Inc. 2014 Incentive Plan, or the 2014 Incentive Plan, and, following this offering, all equity-based awards will be granted under the 2014 Incentive Plan. As of the date of this prospectus, no awards have been made under the 2014 Incentive Plan. The following summary describes the material terms of the 2014 Incentive Plan. This summary of the 2014 Incentive Plan is not a complete description of all provisions of the 2014 Incentive Plan and is qualified in its entirety by reference to the 2014 Incentive Plan, which will be filed as an exhibit to the registration statement of which this prospectus is a part.

**Administration.** The 2014 Incentive Plan is administered by our compensation committee. Our compensation committee has the authority to, among other things, interpret the 2014 Incentive Plan, determine eligibility for, grant and determine the terms of awards under the 2014 Incentive Plan, and do all things necessary or appropriate to carry out the purposes of the 2014 Incentive Plan. Our compensation committee’s determinations under the 2014 Incentive Plan are conclusive and binding.

**Eligibility.** Our key employees, directors, consultants and advisors are eligible to participate in the 2014 Incentive Plan.

**Authorized Shares.** Subject to adjustment, as described below, the maximum number of shares of our common stock that may be delivered in satisfaction of awards under the 2014 Incentive Plan will initially be 1,020,000 shares, plus 111,937 shares that are available for grant under the 2008 Equity Incentive Plan as of the date of the adoption of the Plan. The number of shares of our common stock available for issuance under the 2014 Incentive Plan will be automatically increased annually on January 1 of each calendar year, beginning with the 2015 calendar year and ending with the 2024 calendar year, by an amount equal to three percent (3%) of the number of shares of Stock outstanding on a fully diluted basis as of the close of business on the immediately preceding December 31 (calculated by adding to the number of shares of Stock outstanding, all outstanding securities convertible into

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Stock on such date on an as converted basis). Our board of directors may act prior to January 1 of any year to provide that there will be no automatic increase in the number of shares available for grant under the 2014 Incentive Plan for that year (or that the increase will be less than the amount that would otherwise have automatically been made). Subject to adjustment, as described below, no more than 1,131,937 shares of our common stock may be delivered in satisfaction of incentive stock options, or ISOs, awarded under the 2014 Incentive Plan.

The shares of our common stock to be issued under the 2014 Incentive Plan may be authorized but unissued shares of our common stock or previously issued shares of our common stock acquired by us. Any shares of our common stock underlying awards that are settled in cash, or the portion of any stock option or stock appreciation right, or SAR, that expires, terminates, or is forfeited prior to the issuance of the stock thereunder, will again be available for issuance under the 2014 Incentive Plan. The number of shares of our common stock delivered in satisfaction of awards will be determined by treating as having been delivered the full number of shares of stock covered by any portion of a SAR that is settled in stock (and not only the number of shares of stock delivered in settlement), as well as by treating as having been delivered any shares withheld in payment of the exercise price of an award or in satisfaction of tax withholding requirements with respect to an award.

**Section 162(m) Limits.** The maximum number of shares of our common stock subject to stock options and the maximum number of shares of our common stock subject to SARs that may be granted to any participant in the 2014 Incentive Plan in any calendar year is each 500,000 shares. The maximum number of shares of our common stock subject to other awards that may be granted to any participant in the 2014 Incentive Plan in any calendar year is 167,500 shares.

**Types of Awards.** The 2014 Incentive Plan provides for awards of stock options, SARs, restricted stock, unrestricted stock, stock units, performance awards and other awards convertible into or otherwise based on shares of our common stock. Eligibility for stock options intended to be ISOs is limited to our employees. Dividend equivalents may also be provided in connection with an award under the 2014 Incentive Plan.

- **Stock options and SARs.** The exercise price of a stock option, and the base price against which a SAR is to be measured, may not be less than the fair market value (or, in the case of an ISO granted to a ten percent shareholder, 110% of the fair market value) of shares of our common stock on the date of grant. Our compensation committee will determine the time or times at which stock options or SARs become exercisable and the terms on which such awards remain exercisable. Each stock option and SAR granted under the 2014 Incentive Plan will have a maximum term not to exceed ten (10) years from the date of grant (five (5) years in the case of an ISO granted to a ten percent shareholder).

- **Restricted and unrestricted stock.** A restricted stock award is an award of shares of our common stock subject to forfeiture restrictions, while an unrestricted stock award is not subject to such restrictions.

- **Stock units.** A stock unit award is an award denominated in shares of our common stock that entitles the participant to receive shares of our common stock or cash measured by the value of the shares of our common stock in the future. The delivery of shares of our common stock or cash under a stock unit may be subject to the satisfaction of performance conditions or other vesting conditions.

- **Performance awards.** A performance award is an award the vesting, settlement or exercisability of which is subject to specified performance criteria (meaning, criteria other than the mere passage of time or continuation of the participant's employment or other service relationship).

- **Other awards.** Other awards are awards that are convertible into or otherwise based on shares of our common stock.

**Performance Awards.** The 2014 Incentive Plan provides for the grant of performance awards that are made based upon, and subject to achieving, performance criteria. Performance criteria with respect to those awards that

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are intended to qualify as “performance-based compensation” for purposes of Section 162(m) of the Code, or Section 162(m), to the extent applicable, are limited to an objectively determinable measure or measures of performance relating to any or any combination of the following (measured either absolutely or by reference to an index or indices and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, amortization, or equity expense, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital, capital employed or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; stock price; stockholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures, strategic alliances, licenses or collaborations; spin-offs, split-ups and the like; reorganizations; or recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; manufacturing or process development; or achievement of clinical trial or research objectives, regulatory or other filings or approvals or other product development milestones.

To the extent consistent with the requirements for satisfying the performance-based compensation exception under Section 162(m), to the extent applicable, our compensation committee may provide in the case of any award intended to qualify for such exception that one or more of the performance criteria applicable to such award will be adjusted in an objectively determinable manner to reflect events (for example, the impact of charges for restructurings, discontinued operations, mergers, acquisitions, extraordinary items, and other unusual or non-recurring items, and the cumulative effects of tax or accounting changes, each as defined by U.S. generally accepted accounting principles) occurring during the performance period that affect the applicable performance objectives.

***Vesting; Termination of Employment or Service.*** Our compensation committee has the authority to determine the vesting schedule applicable to each award, and to accelerate the vesting or exercisability of any award. Our compensation committee will determine the effect of termination of employment or service on an award. Unless otherwise provided by our compensation committee, upon a termination of a participant’s employment or service, all unvested stock options and SARs then held by the participant will terminate and all other unvested awards will be forfeited and all vested stock options and SARs then held by the participant will remain outstanding for three months following such termination, or one year in the case of death, or, in each case, until the applicable expiration date, if earlier. All stock options and SARs held by a participant immediately prior to the participant’s termination of employment or service will immediately terminate if such termination is for cause, as defined in the 2014 Incentive Plan, or occurs in circumstances that would have constituted grounds for the participant’s employment or service to be terminated for cause, in the determination of the compensation committee.

***Non-Transferability of Awards.*** Awards under the 2014 Incentive Plan may not be transferred other than by the laws of descent and distribution, unless, for awards other than ISOs, otherwise provided by our compensation committee, and then only to any transferee eligible to be covered by the provisions of Form S-8 (under the Securities Act of 1933).

***Recovery of Compensation.*** Our compensation committee may cancel, rescind, withhold or otherwise limit or restrict any award at any time under the 2014 Incentive Plan if the participant is not in compliance with the provisions of the 2014 Incentive Plan or any award thereunder or if the participant breaches any agreement with our company with respect to non-competition, non-solicitation, confidentiality or invention assignment. Our compensation committee also may recover any award or payments or gain in respect of any award under the 2014 Incentive Plan in accordance with any applicable company recoupment policy or as otherwise required by applicable law or applicable stock exchange listing standards.

***Certain Transactions; Certain Adjustments.*** In the event of a consolidation, merger or similar transaction or series of related transactions, including a sale or other disposition of shares of our common stock, in which we are not the surviving corporation or that results in the acquisition of all or substantially all of our then outstanding shares of common stock by a single person or entity or by a group of persons and/or entities acting in concert, a

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sale of all or substantially all of our assets or our dissolution or liquidation, our compensation committee may, among other things, provide for the continuation or assumption of some or all outstanding awards, for new grants in substitution of outstanding awards, for the accelerated vesting or delivery of shares under awards or for a cash-out of outstanding awards, in each case on such terms and with such restrictions as it deems appropriate. Except as our compensation committee may otherwise determine, awards not assumed in connection with such a transaction will terminate automatically and, in the case of outstanding restricted stock, will be forfeited automatically upon the consummation of such covered transaction. In the event of a stock dividend, stock split or combination of shares, including a reverse stock split, recapitalization or other change in our capital structure that constitutes an equity restructuring within the meaning of FASB ASC 718, our compensation committee will make appropriate adjustments to the maximum number of shares of our common stock that may be delivered under, and the ISO and individual share limits included in, the 2014 Incentive Plan, and will also make appropriate adjustments to the number and kind of shares or securities subject to awards, the exercise prices of such awards or any other terms of awards affected by such change. Our compensation committee will also make the types of adjustments described above to take into account distributions and other events other than those listed above if it determines that such adjustments are appropriate to avoid distortion in the operation of the 2014 Incentive Plan.

**Amendment; Termination.** Our compensation committee will be able to amend the 2014 Incentive Plan or outstanding awards, or terminate the 2014 Incentive Plan as to future grants of awards, except that our compensation committee will not be able to alter the terms of an award if it would affect materially and adversely a participant's rights under the award without the participant's consent (unless expressly provided in the 2014 Incentive Plan or the right to alter the terms of an award was expressly reserved by our compensation committee at the time the award was granted). Shareholder approval will be required for any amendment to the 2014 Incentive Plan to the extent such approval is required by law, including applicable stock exchange requirements. No awards may be made under the 2014 Incentive Plan following the ten (10) year anniversary of its adoption.

### ***Akebia Therapeutics, Inc. Cash Incentive Plan***

On February 28, 2014, our board of directors adopted the Akebia Therapeutics, Inc. Cash Incentive Plan, or the Cash Incentive Plan. Following such date, annual cash award opportunities for executive officers, including our named executive officers, and other key employees will be granted under the Cash Incentive Plan. The following summary describes the material terms of the Cash Incentive Plan. This summary is not a complete description of all provisions of the Cash Incentive Plan and is qualified in its entirety by reference to the Cash Incentive Plan, which will be filed as an exhibit to the registration statement of which this prospectus is a part.

**Administration.** The Cash Incentive Plan will be administered by our compensation committee. Our compensation committee has authority to interpret the Cash Incentive Plan and awards granted under it, to determine eligibility for awards and to do all things necessary to administer the Cash Incentive Plan. Any interpretation or decision by the compensation committee will be final and conclusive on all participants.

**Participants; Individual Limit.** Our executive officers and other key employees will be selected from time to time by the compensation committee to participate in the Cash Incentive Plan. The maximum payment to any participant under the Cash Incentive Plan in any fiscal year will in no event exceed \$2,000,000.

**Awards.** With respect to each award granted under the Cash Incentive Plan, the compensation committee will establish the performance criteria applicable to the award, the amount or amounts payable if the performance criteria are achieved, and such other terms and conditions as the compensation committee deems appropriate. The Cash Incentive Plan permits the grant of awards that are intended to qualify as exempt performance-based compensation under Section 162(m) of the Code, to the extent applicable, as well as awards that are not intended to so qualify. Any awards that are intended to qualify as performance-based compensation will be administered in accordance with the requirements of Section 162(m), to the extent applicable. Awards under the Cash Incentive Plan will not be required to comply with the provisions of the plan applicable to performance-based compensation under Section 162(m) if they are eligible for exemption from such provisions by reason of the transition relief under Section 162(m).

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**Performance Criteria.** Awards under the Cash Incentive Plan will be made based on, and subject to achieving, performance criteria established by our compensation committee, which may be applied to a participant or participants on an individual basis, to a business unit or division, or to the company as a whole. Performance criteria for awards intended to qualify as performance-based compensation for purposes of Section 162(m), to the extent applicable, are limited to the objectively determinable measures of performance relating to any or any combination of the following (measured either absolutely or by reference to an index or indices or the performance of one or more companies and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, amortization, or equity expense, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital, capital employed or assets; one or more operating ratios; operating income or profit, including on an after-tax basis; net income; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; stock price; stockholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures, strategic alliances, licenses or collaborations; spin-offs, split-ups and the like; reorganizations; or recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; manufacturing or process development; or achievement of clinical trial or research objectives, regulatory or other filings or approvals or other product development milestones.

To the extent consistent with the requirements for satisfying the performance-based compensation exception under Section 162(m), to the extent applicable, our compensation committee may provide in the case of any award intended to qualify for such exception that one or more of the performance criteria applicable to such award will be adjusted in an objectively determinable manner to reflect events (for example, the impact of charges for restructurings, discontinued operations, mergers, acquisitions, extraordinary items, and other unusual or non-recurring items, and the cumulative effects of tax or accounting changes, each as defined by U.S. generally accepted accounting principles) occurring during the performance period that affect the applicable performance objectives.

**Payment under an Award.** A participant will be entitled to payment under an award only if all conditions to payment have been satisfied in accordance with the Cash Incentive Plan and the terms of the award. Our compensation committee will determine the payment date or dates for awards under the Cash Incentive Plan. Following the close of the performance period, our compensation committee will determine (and, to the extent required by Section 162(m), certify) whether and to what extent the applicable performance criteria have been satisfied. Our compensation committee will then determine the actual payment, if any, under each award. Our compensation committee has the sole and absolute discretion to reduce the actual payment to be made under any award. Our compensation committee may permit a participant to defer payment of an award subject to the requirements of applicable law.

**Recovery of Compensation.** Awards under the Cash Incentive Plan will be subject to forfeiture, termination and rescission, and a participant who receives a payment pursuant to the Cash Incentive Plan will be obligated to return such payment to us, to the extent provided by our compensation committee in connection with a breach by the participant of the terms of the Cash Incentive Plan, an award agreement under the Cash Incentive Plan or any non-competition, non-solicitation, confidentiality or similar covenant or agreement with our company or an overpayment of incentive compensation due to inaccurate financial data; in accordance with any applicable company recoupment policy; or as otherwise required by law or applicable stock exchange listing standards.

**Amendment; Termination.** Our compensation committee may amend the Cash Incentive Plan at any time, provided that any amendment will be approved by our shareholders if required by Section 162(m). Our compensation committee may terminate the Cash Incentive Plan at any time.

### **2014 Employee Stock Purchase Plan**

In connection with this offering, on February 28, 2014, our board of directors has adopted the Akebia Therapeutics, Inc. 2014 Employee Stock Purchase Plan, or the ESPP, subject to and effective upon approval by

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our shareholders. The ESPP is intended to enable our eligible employees to use payroll deductions to purchase shares of our common stock and thereby acquire an interest in the future of our company. The ESPP is also intended to qualify as an “employee stock purchase plan” under Section 423 of the Code, or Section 423. The following summary describes the material terms of the ESPP. This summary of the ESPP is not a complete description of all provisions of the ESPP and is qualified in its entirety by reference to the ESPP, which is filed as an exhibit to the registration statement of which this prospectus is a part. As of the date of this prospectus, the initial option period under the ESPP has not commenced and our board of directors has not determined the date on which such initial option period will commence.

**Administration.** The ESPP is administered by our compensation committee, which has the authority to interpret the ESPP, determine eligibility under the ESPP, prescribe forms, rules and procedures relating to the ESPP and otherwise do all things necessary or appropriate to carry out the purposes of the ESPP. Our compensation committee’s determinations under the ESPP are final and binding on all participants.

**Eligibility.** Generally, each of our employees (including employees of participating subsidiaries) will be eligible to participate in the ESPP if such employee has been continuously employed by us (or a participating subsidiary) for at least twenty (20) days as of the first day of an option period, customarily works twenty (20) hours or more per week, customarily works for more than five (5) months in any calendar year and satisfies the other requirements set forth in the ESPP. However, an employee may not be granted an option to purchase shares of our common stock under the ESPP if, immediately after the option is granted, the employee would own stock possessing 5% or more of the total combined voting power or value of all classes of our stock.

**Authorized Shares.** Subject to adjustment, as described below, the maximum aggregate number of shares of our common stock available for purchase pursuant to the exercise of options granted under the ESPP will be the lesser of (a) 150,000 shares, increased on each anniversary of the adoption of the ESPP by one percent (1%) of the total shares of our common stock then outstanding and (b) 422,635 shares (which is equal to five percent (5%) of the total shares of our common stock outstanding on the date of adoption of the ESPP on a fully diluted, as converted basis).

**Option Periods.** Unless otherwise determined by the Administrator, the ESPP provides for six-month option periods commencing on the first trading days of January and July and ending on the last trading days of June and December, respectively, of each year. The last day of each such Option Period will be an exercise date. The Administrator may change the exercise date (including the number of exercise dates within each option period) and the commencement date, ending date and duration of the option periods to the extent permitted by applicable law, provided that no exercise date will be later than 7 business days after the end of the applicable option period.

**Option Grant.** Subject to the limitations in the ESPP, participants in the ESPP will be granted an option on the first day of an option period to purchase shares of our common stock on the last day of the option period (i.e., the exercise date). No employee will be granted an option to purchase shares of our common stock under the ESPP if, immediately after the option is granted, he or she would hold rights to purchase shares of our common stock under all our employee stock purchase plans, including the ESPP, that accrue at a rate that exceeds \$25,000 in fair market value for each calendar year.

**Participation.** Eligible employees may participate in the ESPP by executing and delivering to our compensation committee a payroll deduction and participation authorization form in accordance with the rules set forth in the ESPP. Eligible employees may only participate in one option period at a time. A participant may decrease his or her payroll deduction once during an option period. Participants may end their participation in a current option period upon notice to our compensation committee and the accrued payroll deductions will be returned to the participant, without interest. Participation ends automatically upon termination of employment with us.

**Purchase Price.** The purchase price of a share of our common stock issued pursuant to the exercise of an option under the ESPP will be equal to 85% of the lower of the fair market value of our common stock on the first day of the option period or the exercise date.

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**Exercise of Option.** The ESPP will permit participants to purchase shares of our common stock through payroll deductions in whole percentage amounts of up to 15% of their base pay or salary per payroll period. A participant may purchase a maximum of 1,500 shares of our common stock on any exercise date. Subject to the limitations described herein and set forth in the ESPP, on the exercise date of each option period, each participant will be deemed to have exercised his or her option and the participant's accumulated payroll deductions will be applied to purchase shares of our common stock.

**Non-transferable.** A participant may not transfer an option granted under the ESPP.

**Change in capitalization.** In the event of a change in our outstanding shares of common stock due to a stock dividend, split-up, recapitalization, merger, consolidation, reorganization, or other capital change, the aggregate number and type of shares of our common stock available under the ESPP, the number and type of shares granted under any outstanding option, and the purchase price per share under any outstanding option will be appropriately adjusted in a manner that complies with Section 423.

**Merger, sale of assets.** In the event of a sale of all or substantially all of our assets, or a merger or similar transaction in which the company is not the surviving corporation or that results in the acquisition of the company by another person, the compensation committee may, in its discretion, (a) if the company is merged with or acquired by another corporation, provide that each outstanding option will be assumed or exchanged for a substitute option granted by the acquiror or successor corporation, (b) cancel each outstanding option, and/or (c) terminate the option period then in effect.

**Amendment; Termination.** The board has the right to amend, suspend or terminate the ESPP at any time. Unless terminated earlier, the ESPP will automatically terminate in 2024.

### Director Compensation

The following table sets forth a summary of the compensation we paid to our non-employee directors during 2013. Other than as set forth in the table below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the other non-employee members of our board of directors in 2013 and 2012. Mr. Butler, our President and Chief Executive Officer, and Dr. Gardner, our former President and Chief Executive Officer, received no compensation for their service as a director, and, consequently, are not included in this table. The compensation received by Mr. Butler and Dr. Gardner as employees during 2013 and 2012 is presented in "Summary Compensation Table" above.

Name	2013		2012	
	Stock Awards (\$) <sup>(1)</sup>	All Other Compensation (\$) <sup>(2)</sup>	Stock Awards (\$)	All Other Compensation (\$) <sup>(2)</sup>
Anupam Dalal, M.D.	—	6,398	—	5,238
Campbell Murray, M.D.	—	—	—	—
John Rice	—	739	—	863
Paul Weiss	—	927	—	6,000
Jack Nielsen	—	9,236	—	—
Giovanni Ferrara	—	209	—	—
Duane Nash	352,769 <sup>(3)</sup>	—	—	—

- (1) The amount reported in the Stock Awards column represents the retrospective fair value of the stock awards as of the grant date.
- (2) Amounts represent reimbursement of travel and expenses in connection with the individual's service as a director.
- (3) Amount reflects 27,157 shares of restricted stock. Under the terms of the December 23, 2013 restricted stock agreement, 50% of the unvested shares vest on December 23, 2014 and the remaining 50% vests quarterly over the following three years; provided that no shares or restricted stock would vest prior to the occurrence of a liquidity event. Vesting of all restricted shares shall accelerate in connection with an acquisition event pursuant to the terms of the restricted stock agreement. As of December 31, 2013, none of our directors other than the Dr. Nash held stock options or unvested stock awards, and Dr. Nash held 27,157 shares of restricted stock and no stock option.

**Non-Employee Director Compensation Policy**

Our board of directors has adopted a non-employee director compensation policy, effective as of the completion of this offering, that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each individual who is not an employee (a “non-employee director”) will be paid cash compensation from and after the completion of this offering, as set forth below:

	<u>Annual Retainer</u>
<b>Board of Directors:</b>	
All non-employee members	\$35,000
Additional retainer for chair*	\$20,000
<b>Audit Committee:</b>	
Members	\$ 7,500
Additional retainer for chair	\$15,000
<b>Compensation Committee:</b>	
Members	\$ 5,000
Additional retainer for chair	\$10,000
<b>Nominating and Corporate Governance Committee:</b>	
Members	\$ 7,500
Additional retainer for chair	\$ 3,750

\* In the event a non-employee director is one of two concurrently serving chairmen of our board of directors, the annual additional retainer for each co-chair will be \$10,000.

Under our non-employee director compensation policy, each non-employee director who is initially appointed or elected to our board of directors will be eligible to receive a grant of stock option to purchase 10,000 shares of our common stock under our 2014 Incentive Plan at the time of his or her initial appointment or election to our board of directors, which will vest as to 25% of the stock option on the one-year anniversary of the date of grant and the remaining 75% of the stock option will vest ratably on the first day of each calendar quarter between the one-year anniversary of the date of grant and the fourth anniversary of the date of grant, subject to the non-employee director’s continuous service through the applicable vesting date. In addition, each continuing non-employee director who has served on the board of directors for at least six months as of the date of any annual meeting will be eligible to receive, on the date of such annual meeting, a grant of stock options to purchase 5,000 shares of our common stock under our 2014 Incentive Plan, which will vest on the first anniversary of the grant date (or, if earlier, immediately prior to the next annual meeting following the date of grant), subject to the non-employee director’s continuous service through the applicable vesting date. These stock options will be granted with an exercise price equal to the fair market value of a share of our common stock on the date of grant and will have a 10-year term. Our board of directors has adopted a form of stock option award under the 2014 Incentive Plan (as described below) for our non-employee directors, under which initial and subsequent stock option grants will vest in full upon a change in control (as defined in the form of stock option agreement).



### Certain Relationships and Related Party Transactions

Since January 1, 2010, we have engaged in the following transactions with our directors and executive officers and holders of more than 5% of our voting securities and affiliates of our directors, executive officers and such 5% stockholders. We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unaffiliated third parties.

#### Preferred Stock Financings

##### Series A Preferred Stock Financing

In June 2010, we issued and sold an aggregate of 125,000 shares of our Series A preferred stock at a purchase price of \$40.00 per share for an aggregate purchase price of \$5 million. The following table sets forth the number of shares of our Series A preferred stock that we issued to our directors, executive officers and 5% stockholders at the time of such issuance and their affiliates, in connection with this transaction and the aggregate cash purchase price paid by these related parties:

<u>Investor</u>	<u>Shares of Series A Preferred Stock</u>	<u>Purchase Price (\$)</u>
Triathlon Medical Ventures	12,453	498,120
Novartis Bioventures Ltd.	61,250	2,450,000
Venture Investors Early Stage Fund IV	32,747	1,309,889
Kearny Venture Partners, L.P. and affiliates <sup>(1)</sup>	6,806	272,226
Joseph Gardner <sup>(2)</sup>	2,834	113,345
Ian Howes <sup>(3)</sup>	1,250	50,000

- (1) Consists of 3,335 shares purchased by Kearny Venture Partners, L.P., 68 shares purchased by Kearny Venture Partners Entrepreneurs Fund, L.P., and 3,403 shares purchased by Thomas Weisel Healthcare Venture.
- (2) Consists of 625 shares purchased by Joseph Gardner and 2,209 shares purchased by the Gardner Family Trust. Dr. Gardner was our former President and Chief Executive Officer.
- (3) Consists of 1,250 shares purchased by Ian A.W. Howes, IRA, Sterling Trust Custodian. Mr. Howes was our former Chief Financial Officer.

##### Series B Preferred Stock Financing

In April 2011 and December 2011, we issued and sold an aggregate of 1,287,525 shares of our Series B preferred stock at a purchase price of \$14.00 per share for an aggregate purchase price of \$18,025,341. As part of this financing, various trusts and other entities affiliated with Muneer A. Satter collectively purchased 260,873 shares of our Series B preferred stock and immediately following this purchase became a beneficial owner of more than 5% of our voting securities. Furthermore, as part of this financing, AgeChem Venture Fund L.P. purchased 173,915 shares of our Series B preferred stock and immediately following this purchase became a beneficial owner of more than 5% of our voting securities.

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The following table sets forth the number of shares of our Series B preferred stock that we issued to our directors, executive officers and 5% stockholders at the time of such issuance and their affiliates, in connection with this transaction and the aggregate cash purchase price paid by these related parties:

<u>Investor</u>	<u>Shares of Series B Preferred Stock</u>	<u>Purchase Price (\$)</u>
Triathlon Medical Ventures	124,502	1,743,024
Novartis Bioventures Ltd.	347,831	4,869,630
Venture Investors Early Stage Fund IV	173,915	2,434,815
Kearny Venture Partners, L.P. and affiliates <sup>(1)</sup>	88,478	1,238,692
Joseph Gardner <sup>(2)</sup>	18,882	264,354
Robert Shalwitz	2,070	28,986
Ian Howes <sup>(3)</sup>	5,797	81,161

- (1) Consists of 43,355 shares purchased by Kearny Venture Partners, L.P., 884 shares purchased by Kearny Venture Partners Entrepreneurs Fund, L.P., and 44,239 shares purchased by Thomas Weisel Healthcare Venture.
- (2) Consists of 11,594 shares purchased by Joseph Gardner and 7,288 shares purchased by the Gardner Family Trust.
- (3) Consists of 5,797 shares purchased by Ian A.W. Howes, IRA, Sterling Trust Custodian.

### **Series X Preferred Stock Financing**

In July 2012 and March 2013, we issued and sold an aggregate of 50,000 shares of our Series X preferred stock, at a purchase price of \$100.00 per share, for an aggregate purchase price of \$5,000,002.

The following table sets forth the number of shares of our Series X preferred stock that we issued to our directors, executive officers and 5% stockholders at the time of such issuance and their affiliates, in connection with this transaction and the aggregate cash purchase price paid by these related parties:

<u>Investor</u>	<u>Shares of Series X Preferred Stock</u>	<u>Purchase Price (\$)</u>
Triathlon Medical Ventures	6,576	657,576
Novartis Bioventures Ltd.	15,211	1,521,064
Venture Investors Early Stage Fund IV	8,253	825,348
Kearny Venture Partners, L.P. and affiliates <sup>(1)</sup>	4,490	449,004
Trusts and Other Entities Affiliated with Muneer A. Satter	3,504	350,394
Joseph Gardner <sup>(2)</sup>	2,042	204,165
Ian Howes <sup>(3)</sup>	406	40,631
AgeChem Venture Fund L.P.	2,240	224,026

- (1) Consists of 220 shares purchased by Kearny Venture Partners, L.P., 45 shares purchased by Kearny Venture Partners Entrepreneurs Fund, L.P., and 2,245 shares purchased by Thomas Weisel Healthcare Venture.
- (2) Consists of 1,694 shares purchased by Joseph Gardner and 348 shares purchased by the Gardner Family Trust.
- (3) Consists of 406 shares purchased by Ian A.W. Howes, IRA, Sterling Trust Custodian.

### **Series C Preferred Stock Conversion**

In May 2013, we issued an aggregate of 357,143 shares of Series C preferred stock at an exchange rate of 7.14286 shares of Series C preferred stock for every share of Series X preferred stock.

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The following table sets forth the number of shares of our Series C preferred stock that we issued to our directors, executive officers and 5% stockholders at the time of such issuance and their affiliates, in exchange for their shares of Series X preferred stock:

<u>Investor</u>	<u>Shares of Series C Preferred Stock</u>
Triathlon Medical Ventures	6,576
Novartis Bioventures Ltd.	15,211
Venture Investors Early Stage Fund IV	8,253
Kearny Venture Partners, L.P. and affiliates <sup>(1)</sup>	4,490
Trusts and Other Entities Affiliated with Muneer A. Satter	3,504
Joseph Gardner <sup>(2)</sup>	2,042
Ian Howes <sup>(3)</sup>	406
AgeChem Venture Fund L.P.	2,240

(1) Consists of 2,200 shares held by Kearny Venture Partners, L.P., 45 shares held by Kearny Venture Partners Entrepreneurs Fund, L.P., and 2,245 shares held by Thomas Weisel Healthcare Venture.

(2) Consists of 1,694 shares held by Joseph Gardner and 348 shares held by the Gardner Family Trust.

(3) Consists of 406 shares held by Ian A.W. Howes, IRA, Sterling Trust Custodian.

### **Series C Preferred Stock Financing**

In May 2013, we issued and sold an aggregate of 2,945,742 shares of our Series C preferred stock, at a purchase price of \$14.00 per share, for an aggregate purchase price of \$41,240,388. As part of this financing, Novo A/S purchased 714,285 shares of our Series C preferred stock and immediately following this purchase became a beneficial owner of more than 5% of our voting securities.

The following table sets forth the number of shares of our Series C preferred stock that we issued to our directors, executive officers and 5% stockholders at the time of such issuance and their affiliates, in connection with this transaction and the aggregate cash purchase price paid by these related parties:

<u>Investor</u>	<u>Shares of Series C Preferred Stock</u>	<u>Purchase Price (\$)</u>
Triathlon Medical Ventures	71,428	999,992
Novartis Bioventures Ltd.	600,000	8,400,000
Venture Investors Early Stage Fund IV	142,858	2,000,012
Kearny Venture Partners, L.P. and affiliates <sup>(1)</sup>	357,143	5,000,002
Trusts and Other Entities Affiliated with Muneer A. Satter	471,425	6,599,950
Robert Shalwitz	2,500	35,000
Joseph Gardner	14,285	199,990
Ian Howes	7,142	99,988

(1) Consists of 292,733 shares purchased by Kearny Venture Partners, L.P., 5,970 shares purchased by Kearny Venture Partners Entrepreneurs Fund, L.P., and 58,440 shares purchased by Thomas Weisel Healthcare Venture.

### **Indemnification Agreements**

Prior to the completion of this offering, we expect to enter into indemnification agreements with each of our directors and executive officers. These agreements will require us to indemnify these individuals and, in certain cases, affiliates of such individuals, to the fullest extent permissible under Delaware law against liabilities that may arise by reason of their service to us or at our direction, and to advance expenses incurred as a result of any proceeding against them as to which they could be indemnified.

### **Employment Agreements**

See the “Executive Compensation—Employment Agreements with Our Named Executive Officers” section of this prospectus for a further discussion of these agreements.

### **Investors’ Rights Agreement**

In connection with our Series C preferred stock financing, on May 10, 2013, we entered into the Third Amended and Restated Investors’ Rights Agreement, or the investors’ rights agreement, with the holders of all of our then-outstanding shares of preferred stock including certain of our executive officers and entities with which certain of our directors are affiliated. The agreement provides that these holders have the right to demand that we file a registration statement with respect to the common stock issued upon conversion of the preferred stock. These holders may also request that shares of common stock held by them be included in certain registration statements that we are otherwise filing. In connection with this offering, we expect to enter into the Fourth Amended and Restated Investors’ Rights Agreement with the holders of all our outstanding shares of preferred stock including certain of our executive officers and entities with which certain of our directors are affiliated. The Fourth Amended and Restated Investors’ Rights agreement will contain substantially the same terms as the investors’ rights agreement. See “Description of Capital Stock — Registration Rights.”

### **Right of First Refusal and Co-Sale Agreement**

In connection with our Series C preferred stock financing, on May 10, 2013, we entered into an amendment to the Second Amended and Restated Right of First Refusal and Co-Sale Agreement with the holders of all of our then-outstanding shares of preferred stock including certain of our executive officers and entities with which certain of our directors are affiliated. Pursuant to the terms of this agreement, in the event of a proposed sale of shares of our common or preferred stock, the seller is required to first offer such shares to the company and to the other investors, subject to certain conditions and restrictions. This agreement will terminate upon the completion of this offering.

### **Voting Agreement**

In connection with our Series C preferred stock financing on May 10, 2013, we entered into the Third Amended and Restated Voting Agreement with the holders of all of our then-outstanding shares of preferred stock including certain of our executive officers and entities with which certain of our directors are affiliated, with respect to the election of directors and certain other matters. All of our current directors were elected pursuant to the terms of this agreement. This agreement will terminate upon the completion of this offering.

### **Services Agreement**

In connection with the spin out of our programs focused on the treatment of diabetic eye disease and inflammatory bowel disease into Aerpio, we entered into two administrative services agreements with Aerpio, the first on December 22, 2011, as amended and restated on August 27, 2012, and the second on November 1, 2012.

Under the terms of the administrative services agreements, starting in 2012, we and Aerpio have obtained from and provided to each other certain services. These services include consulting services, access to Aerpio’s office facilities in Ohio and Michigan, shared use of IT equipment (including internet and phone networks), and use of Aerpio’s office equipment and furniture. The consulting services include research and development, finance, and administrative services. The agreement also requires the parties to cooperate with each other to facilitate the transition of certain assets, employees and programs to Aerpio in connection with the spin out, and for us to make certain of our employees, including Dr. Shalwitz, our Chief Medical Officer, available for specified amounts of time to work on Aerpio projects.

The scope of consulting services provided to Aerpio under the agreement has declined since 2012, and we anticipate this trend to continue. Aerpio reimbursed us for employee costs in the amount of \$2.0 million for the year ended December 31, 2012 and \$1.0 million for the year ended December 31, 2013. Aerpio paid us for facility related charges in the amount of \$0.2 million for the year ended December 31, 2012 and \$0.3 million

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for the year ended December 31, 2013. We paid Aerpio \$0.2 million for the year ended December 31, 2012, and \$0.3 million for the year ended December 31, 2013. As of December 31, 2013, the amounts due from Aerpio to us total \$135,339, and the amounts due from us to Aerpio total \$62,735.

### **Promissory Notes**

We issued promissory notes to Joseph Gardner, our former President and Chief Executive Officer, in the aggregate amount of \$140,839. Dr. Gardner used these promissory notes to purchase restricted stock awards, as described in “Executive Compensation—2012 Outstanding Equity Awards at Fiscal Year-End.” The promissory notes were amended in 2013 to forgive a portion of the principal owed and to reduce the interest rate from 6% to 3% per annum. As of February 13, 2013, the current balance of the outstanding promissory notes was \$112,831. The promissory notes are repayable at the earlier of (a) an initial public offering; (b) the sale of the company or substantially all of its assets; (c) the termination of the employee; or (d) five years from origination.

### **Related Person Transactions Policy**

Prior to completion of the offering, we will adopt a related person transaction approval policy that will govern the review of related person transactions following the closing of this offering. Pursuant to this policy, if we want to enter into a transaction with a related person or an affiliate of a related person, our Chief Financial Officer will review the proposed transaction to determine, based on applicable NASDAQ and SEC rules, if such transaction requires pre-approval by the audit committee and/or board of directors. If pre-approval is required, such matters will be reviewed at the next regular or special audit committee and/or board of directors meeting. We may not enter into a related person transaction unless our Chief Financial Officer has either specifically confirmed in writing that no further reviews are necessary or that all requisite corporate reviews have been obtained.

**Principal Stockholders**

The following table sets forth information relating to the beneficial ownership of our common stock as of November 30, 2013 by: each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares of common stock; each of our directors; each of our named executive officers; and all directors and executive officers as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of November 30, 2013 through the exercise of any stock options or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The percentage of shares beneficially owned is computed on the basis of 7,260,530 shares of our common stock outstanding as of November 30, 2013, which reflects the assumed conversion of all of our outstanding shares of preferred stock into an aggregate of 6,835,341 shares of common stock. Shares of our common stock that a person has the right to acquire within 60 days of November 30, 2013 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers as a group. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Akebia Therapeutics, Inc., 245 First Street, Suite 1100 Cambridge, MA 02142.

<u>Name and address of beneficial owner</u>	<u>Percentage of shares beneficially owned</u>		
	<u>Number of shares beneficially owned**</u>	<u>Before offering</u>	<u>After offering</u>
<b>5% or greater stockholders:</b>			
Novartis Bioventures Ltd. <sup>(2)</sup>	1,822,996	25.1%	
Venture Investors Early Stage Fund IV <sup>(3)</sup>	823,265	11.3%	
Trusts and Other Entities Affiliated with Muneer A. Satter <sup>(6)</sup>	809,630	11.1%	
Kearny Venture Partners, L.P. and related funds <sup>(4)</sup>	755,437	10.4%	
Novo A/S <sup>(5)</sup>	743,286	10.2%	
Triathlon Medical Ventures <sup>(1)</sup>	634,256	8.7%	
<b>Directors and named executive officers:</b>			
Joseph H. Gardner <sup>(7)</sup>	296,579	4.0%	
John P. Butler	0	*	
William Daly <sup>(8)</sup>	74,910	1.0%	
Robert Shalwitz, M.D. <sup>(9)</sup>	137,596	1.8%	
Muneer A. Satter <sup>(6)</sup>	809,630	11.1%	
Campbell Murray, M.D. <sup>(2)</sup>	1,822,996	25.1%	
Jack Nielsen	0	*	
Anupam Dalal, M.D.	0	*	
Giovanni Ferrara <sup>(2)</sup>	1,822,996	25.1%	
Kim Dueholm	0	*	
Duane Nash	0	*	
Michael S. Wyzga	0	*	
All executive officers and directors as a group (12 persons)	2,770,222	37.4%	

\* Represents beneficial ownership of less than one percent of our outstanding common stock.

\*\* Fractional shares have been rounded down to the nearest whole number.

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- (1) Consists of 20,000 shares of common stock, 365,987 shares of common stock issuable upon conversion of Series A preferred stock, 124,501 shares of common stock issuable upon conversion of Series B preferred stock and 123,768 shares of common stock issuable upon conversion of Series C preferred stock held by Triathlon Medical Ventures Fund. Its general partner, Triathlon Medical Ventures LLC, has sole voting and investment control over the shares owned by Triathlon Medical Ventures Fund. The members of Triathlon Medical Ventures LLC, John Rice, Carrie Bates, Suzette Dutch and Dennis Costello, have sole voting and investment power for Triathlon Medical Ventures LLC with respect to its voting power in its capacity as the general partner for the shares held by Triathlon Medical Ventures Fund.
- (2) Consists of 734,374 shares of common stock issuable upon conversion of Series A preferred stock, 347,830 shares issuable upon conversion of Series B preferred stock and 740,791 shares of common stock issuable upon conversion of Series C preferred stock held by Novartis Bioventures Ltd, a Bermuda corporation. The board of directors of Novartis Bioventures Ltd. has sole voting and investment control and power over such shares. None of the members of its board of directors has individual voting or investment power with respect to such shares and each disclaims beneficial ownership of such shares. Mr. Campbell Murray and Mr. Giovanni Ferrara, two members of our Board of Directors (of which Mr. Murray is co-Chairman), are also employees of a corporation that is affiliated with Novartis Bioventures Ltd. They also disclaim beneficial ownership of shares held by Novartis Bioventures Ltd., except to the extent of their pecuniary interest arising as a result of their employment by that affiliate. Novartis Bioventures Ltd is an indirectly-owned subsidiary of Novartis AG.
- (3) Consists of 438,384 shares of common stock issuable upon conversion of Series A preferred stock, 173,915 shares of common stock issuable upon conversion of Series B preferred stock and 210,965 shares of common stock issuable upon conversion of Series C preferred stock. Venture Investors Early Stage Fund IV Limited Partnership is a Delaware Limited Partnership. Its General Partner, VIESF IV GP LLC, has sole voting and investment control over the shares owned by Venture Investors Early Stage Fund IV Limited Partnership. The members of VIESF IV GP LLC, John Neis, Paul M. Weiss, Scott Button, George Arida, James R. Adox, Loren G. Peterson, and Venture Investors Southeast LLC (of which Roger H. Ganser is the sole member), have sole voting and investment power for VIESF IV GP LLC with respect to its voting power in its capacity as General Partner for the shares held by Venture Investors Early Stage Fund IV Limited Partnership. None of the members of VIESF IV GP LLC has individual voting or investment power with respect to such shares and each disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein. The address of Venture Investors Early Stage Fund IV Limited Partnership is 505 South Rosa Road, Suite 201, Madison, Wisconsin, 53719.
- (4) Consists of (i) 127,446 shares of common stock issuable upon the conversion of Series A preferred stock, 43,354 shares of common stock issuable upon conversion of Series B preferred stock and 322,439 shares of common stock issuable upon conversion of Series C preferred stock that are held directly by Kearny Venture Partners, L.P. (“KVP”), (ii) 2,599 shares of common stock issuable upon the conversion of Series A preferred stock, 884 shares of common stock issuable upon conversion of Series B preferred stock and 6,575 shares of common stock issuable upon conversion of Series C preferred stock held by Kearny Venture Partners Entrepreneurs’ Fund, L.P. (“KVPE”), and (iii) 130,045 shares of common stock issuable upon conversion of Series A preferred stock, 44,239 shares of common stock issuable upon conversion of Series B preferred stock and 77,854 shares of common stock issuable upon conversion of Series C preferred stock that are held directly by Thomas Weisel Healthcare Venture Partners, L.P. (“TWHVP”). Each of KVP, KVPE and TWHVP is a Delaware limited partnership. The general partner of both KVP and KVPE is Kearny Venture Associates, L.L.C. (“KVA”). KVA has the sole voting and investment control over the shares owned by KVP and KVPE, and the Managing Members of KVA share in the voting and investment control over such shares controlled by KVA. The Managing Members of KVA are Caley Castelein, Richard Spalding and James Shapiro. None of the Managing Members of KVA has individual voting or investment power with respect to such shares and each disclaims beneficial

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ownership of such shares except to the extent of any pecuniary interest therein. The address of KVA is 88 Kearny Street, San Francisco, CA 94108. The general partner of TWHVP is Thomas Weisel Healthcare Venture Partners LLC (“TWP GP”). TWP GP has the sole voting and investment control over the shares owned by TWHVP, and the investment committee of TWP GP has sole voting and investment control over the shares controlled by TWP GP. The investment committee of TWP GP consists of Richard Spalding and James Shapiro, neither of whom has individual voting or investment power with respect to such shares and each disclaims beneficial ownership of such shares except to the extent of any pecuniary interest therein. The address of TWP GP is One Montgomery St., San Francisco, CA 94104.

- (5) Consists of 743,286 shares of common stock issuable upon conversion of Series C preferred stock. Novo A/S is a Danish limited liability company. The board of directors of Novo A/S, which consists of Sten Scheibye, Göran Ando, Jørgen Boe, Jeppe Christiansen, Steen Risgaard and Per Wold Olsen, has shared investment and voting control with respect to the shares held by Novo A/S and may exercise such control only with the support of a majority of the members of the Novo A/S board of directors. As such, no individual member of the Novo A/S board of directors is deemed to hold any beneficial ownership or reportable pecuniary interest in the shares held by Novo A/S. Mr. Nielsen and Mr. Dueholm, two members of our board of directors, are employed as Partners of Novo A/S. Neither Mr. Nielsen nor Dr. Dueholm are deemed beneficial owners of, nor do they have a reportable pecuniary interest in, the shares held by Novo A/S. The address of Novo A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.
- (6) Consists of 260,870 shares of common stock issuable upon conversion of Series B preferred stock and 548,759 shares of common stock issuable upon conversion of Series C preferred stock held by Muneer A. Satter Revocable Trust and various other trusts and other entities for which Mr. Satter serves as trustee, investment advisor or manager and, in such capacity, has sole voting and dispositive control over all such shares.
- (7) Joseph Gardner is the Company’s former Chief Executive Officer. This number consists of (i) 48,551 shares of common stock, 78,203 shares of common stock issuable upon the exercise of stock options, 75,220 shares of restricted stock, 25,825 shares of common stock issuable upon conversion of Series A preferred stock, 11,594 shares of common stock issuable upon conversion of Series B preferred stock and 27,579 shares of common stock issuable upon conversion of Series C preferred stock held by Joseph Gardner and (ii) 19,719 shares of common stock issuable upon conversion of Series A preferred stock, 7,288 shares of common stock issuable upon conversion of Series B preferred stock and 2,597 shares of common stock issuable upon conversion of Series C preferred stock held by the Gardner Family Trust.
- (8) Consists of 60,810 shares of restricted stock and 14,100 shares of common stock issuable upon conversion of Series C preferred stock.
- (9) Consists of (i) 4,000 shares of common stock, 59,159 shares of common stock issuable upon the exercise of stock options, 57,604 shares of restricted stock, 2,427 shares of common stock issuable upon conversion of Series A preferred stock, 2,070 shares of common stock issuable upon conversion of Series B preferred stock and 2,613 shares of common stock issuable upon conversion of Series C preferred stock held by Robert Shalwitz and (ii) 9,723 shares of common stock issuable upon conversion of Series A preferred stock held by Fred Shalwitz Trust.



## Description of Capital Stock

### General

The following description of our capital stock is intended as a summary only and is qualified in its entirety by reference to our ninth amended and restated certificate of incorporation and amended and restated bylaws that will be in effect at the closing of this offering, which will be filed as exhibits to the registration statement of which this prospectus is a part, and to the applicable provisions of the Delaware General Corporation Law. We refer in this section to our ninth amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws. The description of our capital stock reflects changes to our capital structure that will occur upon the closing of this offering.

Upon the closing of this offering, our authorized capital stock will consist of 175,000,000 shares of our common stock, par value \$0.00001 per share, and 25,000,000 shares of our preferred stock, par value \$0.00001 per share, all of which preferred stock will be undesignated.

As of December 31, 2013, we had issued and outstanding:

- 790,483 shares of our common stock, which includes 546,965 shares of restricted stock;
- 5,324,948 shares of our preferred stock that are convertible into 6,858,496 shares of our common stock; and
- options to purchase a total of 715,085 shares of our common stock with a weighted-average exercise price of \$1.77 per share.

As of December 31, 2013, we had 44 stockholders of record.

### Common Stock

*Dividend Rights.* Subject to preferences that may apply to shares of preferred stock outstanding at the time, holders of outstanding shares of common stock will be entitled to receive dividends out of assets legally available at the times and in the amounts as the board of directors may from time to time determine.

*Voting Rights.* Each outstanding share of common stock will be entitled to one vote on all matters submitted to a vote of stockholders. Holders of shares of our common stock shall have no cumulative voting rights.

*Conversion or Redemption Rights.* Our common stock will be neither convertible nor redeemable.

*Liquidation Rights.* Upon our liquidation, dissolution or winding up, the holders of our common stock will be entitled to receive pro rata our assets which are legally available for distribution, after payment of all debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

*Rights and Preferences.* Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

### Preferred Stock

All currently outstanding shares of preferred stock will be converted automatically to common stock upon the completion of this offering.

Following the completion of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 25,000,000 shares of preferred stock in one or more series, to establish from

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time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

We have no present plans to issue any shares of preferred stock.

### **Registration Rights**

After our initial public offering, holders of 7,602,743 shares of our common stock issued or issuable (as calculated as of December 31, 2013) will be entitled to certain rights with respect to registration of such shares under the Securities Act. These shares are collectively referred to herein as registrable shares. These rights are provided under the terms of the investors' rights agreement, and include demand registration rights, Form S-3 registration rights and piggyback registration rights. These registration rights are subject to conditions and limitations, including the right, in certain circumstances, of the underwriters of an offering to limit the number of shares included in such registration and our right, in certain circumstances, not to effect a requested S-1 or S-3 registration within 60 days before or 180 days following our estimated date of filing of a registration statement pertaining to an underwritten public offering of securities for the account of an offering of our securities, including this offering.

### ***Demand Registration Rights***

Under the terms of the investors' rights agreement, following the six-month anniversary of the completion of this offering, the holders of at least 30% of the registrable shares may require us to file a registration statement on Form S-1 under the Securities Act at our expense with respect to the resale of their registrable shares as soon as practicable, and in any event within 60 days after the date of the request for registration. We are required to effect only two registrations pursuant to this provision of the investors' rights agreement.

Under the terms of the investors' rights agreement, if we are eligible to file a registration statement on Form S-3, the holders of at least 30% of the registrable shares may require us to file a registration statement on Form S-3 at our expense with respect to the resale of their registrable shares as soon as practicable, and in any event within 45 days after the date of the request for registration. We are required to effect only three registrations pursuant to this provision of the investors' rights agreement.

### ***Piggyback Registration Rights***

Under the terms of the investors' rights agreement, if we propose to register any of our common stock under the Securities Act in connection with the public offering of such securities solely for cash except for certain excluded registrations, the holders of registrable shares are entitled to notice of such registration and to request that we include registrable shares for resale on such registration statement, subject to our right to terminate or withdraw any registration we initiate prior to its effective date and the right of any underwriter to limit the number of shares included in such registration.

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### **Expenses of Registration**

We will pay all expenses relating to any demand, Form S-3 or piggyback registration, other than underwriting discounts, selling commissions and stock transfer taxes applicable to the sale of registrable securities, subject to specified conditions and limitations.

### **Anti-Takeover Effects of Our Certificate of Incorporation and Our Bylaws**

Our certificate of incorporation and bylaws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

These provisions include:

*Classified Board.* Our certificate of incorporation will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon completion of this offering, we expect that our board of directors will have seven members.

*Action by Written Consent; Special Meetings of Stockholders.* Our certificate of incorporation will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and the bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Stockholders will not be permitted to call a special meeting or to require the board of directors to call a special meeting.

*Removal of Directors.* Our certificate of incorporation will provide that our directors may be removed only for cause by the affirmative vote of at least 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

*Advance Notice Procedures.* Our bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws will not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

*Super Majority Approval Requirements.* The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's

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certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. A majority vote of our board of directors or the affirmative vote of holders of at least 75% of the total votes of the outstanding shares of capital stock of the Company entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal the bylaws. In addition, the affirmative vote of the holders of at least 75% of the total votes of the outstanding shares of capital stock of the Company entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal, or to adopt any provisions inconsistent with, any of the provisions in our certificate of incorporation relating to amendments to our certificate of incorporation and bylaws and as described under "Action by Written Consent; Special Meetings of Stockholders", "Classified Board" and "Removal of Directors" above. This requirement of a supermajority vote to approve amendments to our bylaws and certificate of incorporation could enable a minority of our stockholders to exercise veto power over any such amendments.

*Authorized but Unissued Shares.* Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

*Exclusive Forum.* Our certificate of incorporation will provide that, subject to limited exceptions, the state or federal courts located in the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

### **Section 203 of the Delaware General Corporation Law**

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 75% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some

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instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may “opt out” of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders’ amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

### ***Transfer Agent and Registrar***

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

### **Listing**

We have applied to list our common stock on the NASDAQ Global Market under the symbol AKBA.

### Shares Eligible for Future Sale

Prior to this offering, there has been no public market for our common stock. Future sales of our common stock, including shares issued upon the exercise of outstanding options, in the public market after this offering, or the perception that those sales may occur, could cause the prevailing market price for our common stock to fall or impair our ability to raise equity capital at a time and price we deem appropriate. As described below, only a limited number of shares of our common stock will be available for sale in the public market for a period of several months after completion of this offering due to contractual and legal restrictions on resale described below.

#### Sale of Restricted Shares

Based on the number of shares of our common stock outstanding as of December 31, 2013, upon the closing of this offering and assuming (1) the conversion of our outstanding preferred stock into common stock, (2) no exercise of the underwriters' option to purchase additional shares of common stock, and (3) no exercise of outstanding options, we would have had outstanding an aggregate of approximately \_\_\_\_\_ shares of common stock. Of these shares, all of the shares of common stock to be sold in this offering, and any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable in the public market without restriction or further registration under the Securities Act, unless the shares are held by any of our affiliates as such term is defined in Rule 144 of the Securities Act. All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be restricted securities as such term is defined in Rule 144. These restricted securities were issued and sold by us in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, which rules are summarized below.

As a result of the lock-up agreements referred to below and the provisions of Rule 144 and Rule 701 under the Securities Act, the shares of our common stock (excluding the shares sold in this offering) that will be available for sale in the public market are as follows:

<u>Approximate Number of Shares</u>	<u>First Date Available for Sale into Public Market</u>
	180 days after the date of this prospectus upon expiration of the lock-up agreements referred to below, subject in some cases to applicable volume limitations under Rule 144

#### Lock-up Agreements

In connection with this offering, we, and all of our directors and officers, and the holders of substantially all of our outstanding stock and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Credit Suisse Securities (USA) LLC on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus (the "restricted period"):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock,

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and all of our directors and officers, and the holders of substantially all of our common stock and stock options have agreed that, without the prior written consent of

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Morgan Stanley & Co. LLC and Credit Suisse Securities (USA) LLC on behalf of the underwriters, during the restricted period, no registration statement with the SEC relating to the offering of any shares of common stock or any security convertible into or exercisable or exchangeable for our common stock will be filed.

The restrictions described in the immediately preceding paragraph do not apply to:

- the sale of shares by us to the underwriters;
- the issuance by us of shares of our common stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of our common stock; *provided* that such plan does not provide for the transfer of shares of our common stock during the restricted period and to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period;
- transactions relating to shares of our common stock or other securities acquired in this offering (other than any shares of our common stock directed by us and purchased in this offering by one of our officers or directors) or in open market transactions after the date of the final prospectus;
- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, as a bona fide gift;
- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, by will or intestacy;
- the exercise of options to purchase shares of our common stock granted under any existing stock incentive plan or stock purchase plan described in this prospectus, *provided* that any shares of our common stock issued pursuant to such exercise shall be subject to the same restrictions;
- transfers to us for the purpose of satisfying tax withholding obligations upon the vesting of other equity incentive awards granted under any existing stock incentive plan or stock purchase plan described in this prospectus;
- transfers or distributions not involving a disposition for value of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, to any limited or general partners, stockholders or members of a lock-up signatory, or if the lock-up signatory is a corporation, to a wholly-owned subsidiary of such lock-up signatory;
- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, made by one of the lock-up signatories to (i) any trust, corporation, partnership, limited liability company or other legal entity who, directly or indirectly, controls, is controlled by, or is under common control with such lock-up signatory, (ii) any trust or other legal entity for which a lock-up signatory or the spouse of a lock-up signatory serves as trustee or investment advisor, or (iii) any member of the immediate family of a lock-up signatory, or any trust or other legal entity for the direct or indirect benefit of a lock-up signatory or any member of the immediate family of a lock-up signatory;
- transfers of shares of our common stock, or any securities convertible into, exercisable or exchangeable for our common stock, pursuant to a sale of, or an offer to purchase, 100% of our outstanding common stock, whether pursuant to a merger, tender offer or otherwise, to a third party or group of third parties, *provided* that in the event that such tender offer, merger, or transaction is not completed, our common stock and any security convertible into or exchangeable for our common stock shall remain subject to the same restrictions; or

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- the conversion of our outstanding preferred stock into shares of our common stock upon the closing of this offering, *provided* that such shares of our common stock shall remain subject to the same restrictions,

*provided, however*, that in the case of any transfer or distribution pursuant to the fifth, sixth, ninth or tenth clauses above, each donee, distributee or transferee shall sign and deliver a lock-up agreement substantially in the form of the lock-up agreements described above; and in the case of any transaction, transfer, exercise or distribution pursuant to the fourth through (and including) the tenth clauses above, no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of our common stock, shall be required or shall be voluntarily made during the restricted period (other than a filing on Form 5 made after the expiration of the restricted period).

Following the lock-up periods set forth in the agreements described above, all of the shares of our common stock that are restricted securities or are held by our affiliates as of the date of this prospectus will be eligible for sale in the public market in compliance with Rule 144 under the Securities Act.

In addition to the restrictions contained in the lock-up agreements described above, we have entered into agreements with certain of our security holders, including our amended and restated investors rights agreement and the standard forms of our option agreements under our equity incentive plans, that contain market stand-off provisions imposing restrictions on the ability of such security holders to offer, sell or transfer our equity securities for a period of 180 days following the date of this prospectus.

### **Rule 144**

#### ***Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours, or who was an affiliate at any time during the 90 days before a sale, who has beneficially owned shares of our common stock for at least six months would be entitled to sell in “broker’s transactions” or certain “riskless principal transactions” or to market makers, a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately        shares immediately after this offering; or
- the average weekly trading volume in our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Affiliate resales under Rule 144 are also subject to the availability of current public information about us. In addition, if the number of shares being sold under Rule 144 by an affiliate during any three-month period exceeds 5,000 shares or has an aggregate sale price in excess of \$50,000, the seller must file a notice on Form 144 with the Securities and Exchange Commission and NASDAQ concurrently with either the placing of a sale order with the broker or the execution directly with a market maker.

#### ***Non-Affiliate Resales of Restricted Securities***

In general, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is not an affiliate of ours at the time of sale, and has not been an affiliate at any time during the 90 days preceding a sale, and who has beneficially owned shares of our common stock for at least six months but less than a year, is entitled to sell such shares subject only to the availability of current public information about us. If such person has held our shares for at least one year, such person can resell under Rule 144(b)(1) without regard to any Rule 144 restrictions, including the 90-day public company requirement and the current public information requirement.



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Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### **Rule 701**

In general, under Rule 701, any of an issuer's employees, directors, officers, consultants or advisors who purchases shares from the issuer in connection with a qualified compensatory stock or option plan or other written agreement before the effective date of a registration statement under the Securities Act is entitled to sell such shares 90 days after such effective date in reliance on Rule 144. An affiliate of the issuer can resell shares in reliance on Rule 144 without having to comply with the holding period requirement, and non-affiliates of the issuer can resell shares in reliance on Rule 144 without having to comply with the current public information and holding period requirements.

The Securities and Exchange Commission has indicated that Rule 701 will apply to stock options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after an issuer becomes subject to the reporting requirements of the Exchange Act.

### **Registration Rights**

Upon the completion of this offering, the holders of 7,602,743 shares of our common stock issued or issuable (as calculated as of December 31, 2013) will be entitled to specified rights with respect to the registration of the offer and sale of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration statement. See the section of this prospectus titled "Description of Capital Stock—Registration Rights" for additional information.

### **Equity Incentive Plans**

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock that we may issue upon exercise of outstanding options or options or other equity awards to be issued under our Amended and Restated 2008 Equity Incentive Plan and 2014 Incentive Plan. Such registration statement is expected to be filed and become effective as soon as practicable after the completion of this offering. Accordingly, shares registered under such registration statement will be available for sale in the open market following its effective date, subject to Rule 144 restrictions on affiliates and the lock-up agreements described above, if applicable.

**Material United States Federal Income Tax  
Considerations for Non-U.S. Holders**

The following is a summary of the material U.S. federal income and estate tax considerations relating to the purchase, ownership and disposition of our common stock by Non-U.S. Holders (defined below). This summary does not purport to be a complete analysis of all the potential tax considerations relevant to Non-U.S. Holders of our common stock. This summary is based upon the Code, the Treasury regulations promulgated or proposed thereunder and administrative and judicial interpretations thereof, all as of the date hereof and all of which are subject to differing interpretations and to change at any time, possibly on a retroactive basis.

This summary assumes that shares of our common stock are held as “capital assets” within the meaning of Section 1221 of the Code (generally, property held for investment). This summary does not purport to deal with all aspects of U.S. federal income and estate taxation that might be relevant to particular Non-U.S. Holders in light of their particular investment circumstances or status, nor does it address specific tax considerations that may be relevant to particular persons (including, for example, financial institutions, broker-dealers, insurance companies, partnerships or other pass-through entities, certain U.S. expatriates, tax-exempt organizations, pension plans, “controlled foreign corporations”, “passive foreign investment companies”, corporations that accumulate earnings to avoid U.S. federal income tax, persons in special situations, such as those who have elected to mark securities to market or those who hold common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment, or holders subject to the alternative minimum tax or the 3.8% Medicare tax on net investment income). In addition, except as explicitly addressed herein with respect to estate tax, this summary does not address estate and gift tax considerations or considerations under the tax laws of any state, local or non-U.S. jurisdiction.

For purposes of this summary, a “Non-U.S. Holder” means a beneficial owner of common stock that for U.S. federal income tax purposes is not an entity treated as a partnership and is not:

- an individual who is a citizen or resident of the United States;
- a corporation or any other organization taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is included in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust if (1) a U.S. court is able to exercise primary supervision over the trust’s administration and one or more U.S. persons have the authority to control all of the trust’s substantial decisions or (2) the trust has a valid election in effect under applicable Treasury regulations to be treated as a U.S. person.

If an entity that is treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of persons treated as its partners for U.S. federal income tax purposes will generally depend upon the status of the partner and the activities of the partnership. Entities that are treated as partnerships for U.S. federal income tax purposes and persons holding our common stock through an entity treated as a partnership for U.S. federal income tax purposes are urged to consult their own tax advisors.

There can be no assurance that the Internal Revenue Service (“IRS”) will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain a ruling from the IRS with respect to the U.S. federal income or estate tax consequences to a Non-U.S. Holder of the purchase, ownership or disposition of our common stock.

**THIS SUMMARY IS NOT INTENDED TO BE TAX ADVICE. NON-U.S. HOLDERS ARE URGED TO CONSULT THEIR TAX ADVISORS CONCERNING THE U.S. FEDERAL INCOME AND ESTATE TAXATION, STATE, LOCAL AND NON-U.S. TAXATION AND OTHER TAX CONSEQUENCES TO THEM OF THE PURCHASE, OWNERSHIP AND DISPOSITION OF OUR COMMON STOCK.**

## Distributions on Our Common Stock

As discussed under “Dividend Policy” above, we do not anticipate paying any cash dividends in the foreseeable future. In the event that we do make a distribution of cash or property (other than certain stock distributions) with respect to our common stock (or in the case of certain redemptions that are treated as distributions with respect to our common stock), any such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent of our current and accumulated earnings and profits, if any, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will constitute a return of capital and will first reduce the holder’s adjusted tax basis in our common stock, but not below zero. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “—Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock”. Any such distribution would also be subject to the discussion below under the sections titled “—Additional Withholding and Reporting Requirements” and “—Backup Withholding and Information Reporting.”

Dividends paid to a Non-U.S. Holder generally will be subject to a 30% U.S. federal withholding tax unless such Non-U.S. Holder provides us or another applicable withholding agent, as the case may be, with the appropriate IRS Form W-8, such as:

- IRS Form W-8BEN (or successor form) certifying, under penalties of perjury, that such holder is not a United States person (as defined under the Code) and is eligible for a reduction in the rate of, or exemption from, withholding under an applicable income tax treaty, or
- IRS Form W-8ECI (or successor form) certifying that a dividend paid on common stock is not subject to withholding tax because it is effectively connected with a trade or business in the United States of the Non-U.S. Holder (in which case such dividend generally will be subject to regular graduated U.S. tax rates as described below).

The certification requirement described above must be provided to us or another applicable withholding agent prior to the payment of dividends and must be updated periodically. The certification also may require a Non-U.S. Holder that claims treaty benefits of a reduction in the rate of, or exemption from, withholding on dividends to provide its U.S. taxpayer identification number. Special certification and other requirements apply in the case of certain Non-U.S. Holders that hold shares of our common stock through intermediaries or are pass-through entities for U.S. federal income tax purposes.

Each Non-U.S. Holder is urged to consult its own tax advisor about the specific methods for satisfying these requirements. A claim for exemption will not be valid if the person receiving the applicable form has actual knowledge or reason to know that the statements on the form are false.

If dividends are effectively connected with a trade or business in the United States of a Non-U.S. Holder (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base), the Non-U.S. Holder, although exempt from the withholding tax described above (provided that the certifications described above are satisfied), generally will be subject to U.S. federal income tax on such dividends on a net income basis in the same manner as if it were a U.S. person. In addition, if a Non-U.S. Holder is treated as a corporation for U.S. federal income tax purposes, the Non-U.S. Holder may be subject to an additional “branch profits tax” equal to 30% (unless reduced by an applicable income tax treaty) of such effectively connected dividend, as adjusted for certain items.

Non-U.S. Holders that do not timely provide us or another applicable withholding agent with the required certification, but which are eligible for a reduced rate of, or an exemption from, U.S. federal withholding tax, may obtain a refund or credit of any excess amount withheld by timely filing an appropriate claim for refund with the IRS.

### **Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock**

Subject to the discussion below under the sections titled “—Additional Withholding and Reporting Requirements” and “—Backup Withholding and Information Reporting”, in general, a Non-U.S. Holder will not be subject to U.S. federal income tax or withholding tax on gain realized upon such holder’s sale, exchange or other taxable disposition of shares of our common stock unless (i) such Non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition, and certain other conditions are met; (ii) we are or have been a “United States real property holding corporation”, as defined in the Code (a “USRPHC”), at any time within the shorter of the five-year period preceding the disposition and the Non-U.S. Holder’s holding period in the shares of our common stock, and certain other requirements are met; or (iii) such gain is effectively connected with the conduct by such Non-U.S. Holder of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained by such Non-U.S. Holder in the United States).

If the first exception applies, the Non-U.S. Holder generally will be subject to U.S. federal income tax at a rate of 30% (or at a reduced rate under an applicable income tax treaty) on the amount by which such Non-U.S. Holder’s capital gains allocable to U.S. sources exceed capital losses allocable to U.S. sources during the taxable year of the disposition. If the third exception applies, the Non-U.S. Holder generally will be subject to U.S. federal income tax with respect to such gain on a net income basis in the same manner as if it were a U.S. person, and a Non-U.S. Holder that is a corporation for U.S. federal income tax purposes may also be subject to a branch profits tax with respect to such effectively connected gain, as adjusted for certain items, at a rate of 30% (or at a reduced rate under an applicable income tax treaty).

Regarding the second exception, generally, a corporation is a USRPHC only if the fair market value of its U.S. real property interests (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance in this regard, we believe that we are not, and do not anticipate becoming, a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other business assets, there can be no assurance that we have not been a USRPHC in the past and will not become a USRPHC in the future. Even if we became a USRPHC, a Non-U.S. Holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of our common stock by reason of our status as USRPHC so long as our common stock is regularly traded on an established securities market (within the meaning of the applicable regulations) and such Non-U.S. Holder does not own and is not deemed to own (directly, indirectly or constructively) more than 5% of our outstanding common stock at any time during the shorter of the five year period ending on the date of disposition and such holder’s holding period. However, no assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above. Prospective investors are encouraged to consult their own tax advisors regarding the possible consequences to them if we are, or were to become, a USRPHC.

### **Additional Withholding and Reporting Requirements**

Legislation enacted in March 2010 and related guidance (commonly referred to as “FATCA”) will impose, in certain circumstances, U.S. federal withholding at a rate of 30% on payments of (a) dividends on our common stock on or after July 1, 2014, and (b) gross proceeds from the sale or other disposition of our common stock on or after January 1, 2017. In the case of payments made to a “foreign financial institution” as defined under FATCA (including, among other entities, an investment fund), the tax generally will be imposed, subject to certain exceptions, unless such institution (i) enters into (or is otherwise subject to) and complies with an agreement with the U.S. government (a “FATCA Agreement”) or (ii) complies with an applicable intergovernmental agreement between the United States and a foreign jurisdiction (an “IGA”) or any foreign law implementing an applicable IGA, in either case to, among other things, collect and provide to the U.S. or other relevant tax authorities certain information regarding U.S. account holders of such institution. In the case of

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payments made to a foreign entity that is not a foreign financial institution, the tax generally will be imposed, subject to certain exceptions, unless such foreign entity provides the withholding agent with a certification that it does not have any “substantial U.S. owners” (generally, any specified U.S. persons that directly or indirectly owns more than a specified percentage of such entity) or that identifies its substantial U.S. owners. If our common stock is held through a foreign financial institution that enters into (or is otherwise subject to) a FATCA Agreement, such foreign financial institution (or, in certain cases, a person paying amounts to such foreign financial institution) generally will be required, subject to certain exceptions, to apply FATCA withholding on payments of dividends and proceeds described above made to (x) a person (including an individual) that fails to comply with certain information requests or (y) a foreign financial institution that has not entered into a FATCA Agreement and is not otherwise exempt from FATCA pursuant to an IGA.

Prospective investors should consult their own tax advisors regarding the possible impact of these rules on their investment in our common stock, and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of this 30% withholding tax under FATCA.

### **Backup Withholding and Information Reporting**

We must report annually to the IRS and to each Non-U.S. Holder the gross amount of the distributions on our common stock paid to the holder and the tax withheld, if any, with respect to the distributions. Non-U.S. Holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate, currently 28%, with respect to dividends on our common stock. Dividends paid to Non-U.S. Holders subject to U.S. withholding, as described above under the section titled “—Distributions on Our Common Stock”, generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a Non-U.S. Holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies, under penalties of perjury, that it is not a United States person (as defined under the Code) and satisfies certain other requirements (and the payor does not have actual knowledge or reason to know that the beneficial owner is a United States person), or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Prospective investors should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the Non-U.S. Holder resides or in which the Non-U.S. Holder is incorporated, under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder can be refunded or credited against the Non-U.S. Holder’s U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

### **Federal Estate Tax**

Common stock owned (or treated as owned) by an individual who is not a citizen or a resident of the United States (as defined for U.S. federal estate tax purposes) at the time of death will be included in the individual’s gross estate for U.S. federal estate tax purposes unless an applicable estate or other tax treaty provides otherwise, and therefore, may be subject to U.S. federal estate tax.

### Underwriting

Under the terms and subject to the conditions in an underwriting agreement to be dated the date of the final prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, Credit Suisse Securities (USA) LLC and UBS Securities LLC are acting as representatives, will severally agree to purchase, and we will agree to sell to them, severally, the number of shares indicated below:

<u>Name</u>	<u>Number of Shares</u>
Morgan Stanley & Co. LLC	
Credit Suisse Securities (USA) LLC	
UBS Securities LLC	
Nomura Securities International, Inc.	
Total	

The underwriters and the representatives are collectively referred to as the “underwriters” and the “representatives,” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters’ over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$ \_\_\_\_\_ a share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to \_\_\_\_\_ additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional \_\_\_\_\_ shares of common stock.

	<u>Per Share</u>	<u>Total</u>	
		<u>No exercise</u>	<u>Full exercise</u>
Public Offering Price	\$ _____	\$ _____	\$ _____
Underwriting Discount and commissions to be paid by us	\$ _____	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____	\$ _____

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$ \_\_\_\_\_ million. We have agreed to reimburse the underwriters for expenses relating to clearance of

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this offering with the Financial Industry Regulatory Authority, Inc. and the qualification of our common stock under state securities laws (in an amount not to exceed in the aggregate \$50,000).

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We have applied to have our common stock listed on the Nasdaq Global Market under the trading symbol AKBA.

We, and all of our directors and officers, and the holders of substantially all of our outstanding stock and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Credit Suisse Securities (USA) LLC on behalf of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus (the “restricted period”):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock,

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and all of our directors and officers, and the holders of substantially all of our common stock and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Credit Suisse Securities (USA) LLC on behalf of the underwriters, during the restricted period, no registration statement with the SEC relating to the offering of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock will be filed.

The restrictions described in the immediately preceding paragraph to do not apply to:

- the sale of shares by us to the underwriters;
- the issuance by us of shares of our common stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date of this prospectus of which the Underwriters have been advised in writing;
- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of our common stock; *provided* that such plan does not provide for the transfer of shares of our common stock during the restricted period and to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period;
- transactions relating to shares of our common stock or other securities acquired in this offering (other than any shares of our common stock directed by us and purchased in this offering by one of our officers or directors) or in open market transactions after the date of the final prospectus;
- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, as a bona fide gift;
- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, by will or intestacy;
- the exercise of options to purchase shares of our common stock granted under any existing stock incentive plan or stock purchase plan described in this prospectus, *provided* that any shares of our common stock issued pursuant to such exercise shall be subject to the same restrictions;

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- transfers to us for the purpose of satisfying tax withholding obligations upon the vesting of other equity incentive awards granted under any existing stock incentive plan or stock purchase plan described in this prospectus;
- transfers or distributions not involving a disposition for value of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, to any limited or general partners, stockholders or members of a lock-up signatory, or if the lock-up signatory is a corporation, to a wholly-owned subsidiary of such lock-up signatory;
- transfers of shares of our common stock, or any security convertible into, exercisable or exchangeable for our common stock, made by one of the lock-up signatories to (i) any trust, corporation, partnership, limited liability company or other legal entity who, directly or indirectly, controls, is controlled by, or is under common control with such lock-up signatory, (ii) any trust or other legal entity for which a lock-up signatory or the spouse of a lock-up signatory serves as trustee or investment advisor, or (iii) any member of the immediate family of a lock-up signatory, or any trust or other legal entity for the direct or indirect benefit of a lock-up signatory or any member of the immediate family of a lock-up signatory;
- transfers of shares of our common stock, or any securities convertible into, exercisable or exchangeable for our common stock, pursuant to a sale of, or an offer to purchase, 100% of our outstanding common stock, whether pursuant to a merger, tender offer or otherwise, to a third party or group of third parties, *provided* that in the event that such tender offer, merger, or transaction is not completed, our common stock and any security convertible into or exchangeable for our common stock shall remain subject to the same restrictions; or
- the conversion of our outstanding preferred stock into shares of our common stock upon the closing of this offering, *provided* that such shares of our common stock shall remain subject to the same restrictions,

*provided, however*, that in the case of any transfer or distribution pursuant to the fifth, sixth, ninth or tenth clauses above, each donee, distributee or transferee shall sign and deliver a lock-up agreement substantially in the form of the lock-up agreements described above; and in the case of any transaction, transfer, exercise or distribution pursuant to the fourth through (and including) the tenth clauses above, no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of our common stock, shall be required or shall be voluntarily made during the restricted period (other than a filing on Form 5 made after the expiration of the restricted period).

Morgan Stanley & Co. LLC and Credit Suisse Securities (USA) LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize



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the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

### **Other Relationships**

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

### **Pricing of the Offering**

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities and certain financial and operating information of companies engaged in activities similar to ours.

### **Directed Share Program**

At our request, the underwriters have reserved 5% of the shares of common stock to be issued by us and offered by this prospectus for sale, at the initial public offering price, to directors, officers, employees, business associates and related persons of Akebia Therapeutics, Inc. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.

### **Selling Restrictions**

#### ***European Economic Area***

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any shares of our common stock may not

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be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any shares of our common stock may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- (b) to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of shares of our common stock shall result in a requirement for the publication by us or any underwriter of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares of our common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares of our common stock to be offered so as to enable an investor to decide to purchase any shares of our common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State, the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State, and the expression “2010 PD Amending Directive” means Directive 2010/73/EU.

### **United Kingdom**

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 (“FSMA”)) received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

### **Switzerland**

The Prospectus does not constitute an issue prospectus pursuant to Article 652a or Article 1156 of the Swiss Code of Obligations (“CO”) and the shares will not be listed on the SIX Swiss Exchange. Therefore, the Prospectus may not comply with the disclosure standards of the CO and/or the listing rules (including any prospectus schemes) of the SIX Swiss Exchange. Accordingly, the shares may not be offered to the public in or from Switzerland, but only to a selected and limited circle of investors, which do not subscribe to the shares with a view to distribution.

### **Legal Matters**

The validity of the common stock offered in this prospectus will be passed upon for us by Ropes & Gray LLP, Boston, Massachusetts. Certain legal matters in connection with this offering will be passed upon for the underwriters by Latham & Watkins LLP, Boston, Massachusetts.

### **Experts**

The financial statements of Akebia Therapeutics, Inc. (a development stage company) at December 31, 2013 and 2012, and for each of the two years in the period ended December 31, 2013, and for the period February 27, 2007 (inception) through December 31, 2013, appearing in this Prospectus and Registration Statement have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

### **Where You Can Find More Information**

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed therewith. For further information with respect to us and the common stock offered hereby, reference is made to the registration statement and the exhibits and schedules filed therewith. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. A copy of the registration statement and the exhibits and schedules filed therewith may be inspected without charge at the public reference room maintained by the SEC, located at 100 F Street N.E., Washington, D.C. 20549, and copies of all or any part of the registration statement may be obtained from such offices upon the payment of the fees prescribed by the SEC. Please call the SEC at 1-800-SEC-0330 for further information about the public reference room. The SEC also maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address is [www.sec.gov](http://www.sec.gov).

Upon completion of this offering, we will become subject to the information and periodic reporting requirements of the Exchange Act and, in accordance therewith, will file periodic reports, proxy statements and other information with the SEC. Such periodic reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above.

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**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders of  
Akebia Therapeutics, Inc.

We have audited the accompanying balance sheets of Akebia Therapeutics, Inc. (a development stage company) as of December 31, 2013 and 2012, and the related statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2013, and for the period from February 27, 2007 (inception) through December 31, 2013. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Akebia Therapeutics, Inc. (a development stage company) at December 31, 2013 and 2012, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2013 and for the period from February 27, 2007 (inception) through December 31, 2013, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Cincinnati, Ohio  
February 14, 2014

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**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Balance Sheets**

	<u>December 31, 2012</u>	<u>December 31, 2013</u>	
		<u>Actual</u>	<u>Pro forma (unaudited)</u>
<b>Assets</b>			
Current assets:			
Cash and cash equivalents	\$ 1,641,038	\$ 21,215,228	\$ 21,215,228
Investments	—	11,341,241	11,341,241
Accounts receivable	85,633	135,339	135,339
Prepaid expenses and other current assets	517,202	739,235	739,235
Total current assets	2,243,873	33,431,043	33,431,043
Equipment, net of accumulated depreciation of \$1,282 at December 31, 2013	—	30,366	30,366
Deferred offering costs	—	1,078,138	1,078,138
Other assets	—	125,345	125,345
Total assets	<u>\$ 2,243,873</u>	<u>\$ 34,664,892</u>	<u>\$ 34,664,892</u>
<b>Liabilities, redeemable convertible preferred stock and stockholders' deficit</b>			
Current liabilities:			
Accounts payable	\$ 417,943	\$ 714,137	\$ 714,137
Accrued expenses	351,250	3,183,761	3,183,761
Current portion of capital lease obligation	—	3,912	3,912
2012 Series X preferred stock subject to mandatory redemption	4,154,137	—	—
Total current liabilities	4,923,330	3,901,810	3,901,810
Capital lease obligation, net of current portion	—	8,004	8,004
Total liabilities	\$ 4,923,330	\$ 3,909,814	\$ 3,909,814
Commitments and contingencies (see Note 11)			
Redeemable convertible preferred stock; \$.00001 par value; 2,427,394 and 5,500,636 shares authorized at December 31, 2012 and December 31, 2013, respectively:			
Series A redeemable convertible preferred stock; 734,538 shares issued and outstanding at December 31, 2012 and December 31, 2013; no shares issued and outstanding pro forma (unaudited); (Aggregate liquidation preference of \$39,367,094 at December 31, 2013)	37,092,486	39,367,094	—
Series B redeemable convertible preferred stock; 1,287,525 shares issued and outstanding at December 31, 2012 and December 31, 2013; no shares issued and outstanding pro forma (unaudited); (Aggregate liquidation preference of \$21,031,365 at December 31, 2013)	19,816,185	21,257,044	—
Series C redeemable convertible preferred stock; no shares issued and outstanding at December 2012; 3,302,885 shares issued and outstanding at December 31, 2013; no shares issued and outstanding pro forma (unaudited); (Aggregate liquidation preference of \$97,202,997 at December 31, 2013)	—	97,202,997	—
Total redeemable convertible preferred stock	56,908,671	157,827,135	—
Stockholders' (deficit) equity:			
Common stock; \$.00001 par value; 4,466,956 and 8,400,000 authorized at December 31, 2012 and December 31, 2013, respectively; 351,861 and 790,483 shares issued and outstanding at December 31, 2012 and December 31, 2013, respectively; 7,648,979 shares issued and outstanding pro forma (unaudited)	3	7	76
Additional paid-in capital	—	—	94,461,641
Deficit accumulated during the development stage	(59,588,131)	(127,072,064)	(63,706,639)
Total stockholders' (deficit) equity	<u>(59,588,128)</u>	<u>(127,072,057)</u>	<u>30,755,078</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity	<u>\$ 2,243,873</u>	<u>\$ 34,664,892</u>	<u>\$ 34,664,892</u>

See accompanying notes to financial statements.

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**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Statements of Operations and Comprehensive Loss**

	<u>Year Ended December 31,</u>		<b>February 27,</b>
	<u>2012</u>	<u>2013</u>	<b>(inception) through December 2013</b>
Revenue	\$ —	\$ —	\$ —
Operating expenses:			
Research and development	5,631,541	10,781,600	51,747,845
General and administrative	2,891,008	5,151,621	15,268,937
Total operating expenses	<u>8,522,549</u>	<u>15,933,221</u>	<u>67,016,782</u>
Operating loss	(8,522,549)	(15,933,221)	(67,016,782)
Other income (expense):			
Grant income	—	—	1,481,408
Interest expense, net	(1,644,654)	(703,569)	(4,916,597)
Extinguishment of debt and other liabilities	—	2,419,766	3,735,499
Reimbursements from Aerpio	1,971,246	1,049,844	3,021,090
Gain on cancellation of preferred stock future tranche rights	—	—	653,465
Net loss and comprehensive loss	<u>\$ (8,195,957)</u>	<u>\$ (13,167,180)</u>	<u>\$ (63,041,917)</u>
Reconciliation of net loss to net loss applicable to common stockholders:			
Net loss	\$ (8,195,957)	\$ (13,167,180)	\$ (63,041,917)
Accretion on preferred stock	(3,322,647)	(55,885,844)	(66,738,199)
Loss on extinguishment of preferred stock	—	—	(597,174)
Net loss applicable to common stockholders	<u>\$ (11,518,604)</u>	<u>\$ (69,053,024)</u>	<u>\$ (130,377,290)</u>
Net loss per share applicable to common stockholders—basic and diluted	<u>\$ (48.68)</u>	<u>\$ (222.14)</u>	<u>\$ (841.82)</u>
Weighted-average number of common shares used in net loss per share applicable to common stockholders’—basic and diluted	236,633	310,858	154,875
Pro forma net loss applicable to common stockholders (unaudited)		<u>\$ (13,304,154)</u>	
Pro forma net loss per share applicable to common stockholders—basic and diluted (unaudited)		<u>\$ (2.30)</u>	
Pro forma weighted-average number of common shares used in pro forma net loss per share applicable to common stockholders—basic and diluted (unaudited)		<u>5,790,016</u>	

See accompanying notes to financial statements.

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**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Preferred Stock and Stockholders' Equity (Deficit)**  
**Period from February 27, 2007 (inception) through December 31, 2013**

	Redeemable Convertible Preferred Stock								Stockholders' Equity (Deficit)						
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		2012 Series X Convertible Preferred Stock		2007 Series X Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	\$0.00001 Par Value	Number of Shares	\$0.00001 Par Value			
Initial capital contribution	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	40,000	\$ —	\$ 40	\$ —	\$ 40
Issuance of 2007 Series X convertible preferred stock	—	—	—	—	—	—	—	—	9,938	—	—	—	31,800	—	31,800
Issuance costs associated with sale of Series A redeemable convertible preferred stock	—	—	—	—	—	—	—	—	—	—	—	—	(21,219)	—	(21,219)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(2,701,292)	(2,701,292)
Balance at December 31, 2007	—	—	—	—	—	—	—	—	9,938	—	40,000	—	10,621	(2,701,292)	(2,690,671)
Sale of Series A preferred stock, net of issuance costs of \$90,453	226,500	8,359,507	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series A preferred stock in settlement of convertible notes	45,228	1,626,386	—	—	—	—	—	—	—	—	—	—	—	—	—
Accretion of preferred stock to redemption value	—	1,515,495	—	—	—	—	—	—	—	—	—	—	(649,509)	(865,986)	(1,515,495)
Loss on extinguishment of 2007 Series X convertible preferred stock	—	—	—	—	—	—	—	—	—	—	—	—	597,174	(597,174)	—
Conversion of 2007 Series X convertible preferred stock into common stock	—	—	—	—	—	—	—	—	(9,938)	—	72,047	1	(1)	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	41,715	—	41,715
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(5,076,316)	(5,076,316)
Balance at December 31, 2008	271,728	11,501,388	—	—	—	—	—	—	—	—	112,047	1	—	(9,240,768)	(9,240,767)
Sale of Series A preferred stock, net of issuance costs of \$44,008	265,609	10,525,461	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of Series A preferred stock in settlement of convertible notes	72,201	2,851,929	—	—	—	—	—	—	—	—	—	—	—	—	—
Accretion of preferred stock to redemption value	—	1,226,217	—	—	—	—	—	—	—	—	—	—	(104,737)	(1,121,480)	(1,226,217)
Issuance of restricted common stock	—	—	—	—	—	—	—	—	—	—	31,474	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	104,737	—	104,737
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,506,556)	(8,506,556)
Balance at December 31, 2009	609,538	26,104,995	—	—	—	—	—	—	—	—	143,521	1	—	(18,868,804)	(18,868,803)



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**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**Period from February 27, 2007 (inception) through December 31, 2013**

	Redeemable Convertible Preferred Stock								Stockholders' Equity (Deficit)						
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		2012 Series X Convertible Preferred Stock		2007 Series X Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	\$0.00001 Par Value	Number of Shares	\$0.00001 Par Value			
Sale of Series A preferred stock, net of issuance costs of \$29,403	125,000	\$ 4,970,597	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	\$ —	\$ —	\$ —
Accretion of preferred stock to redemption value	—	1,817,410	—	—	—	—	—	—	—	—	—	—	(169,271)	(1,648,139)	(1,817,410)
Issuance of restricted common stock	—	—	—	—	—	—	—	—	—	—	10,603	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	169,271	—	169,271
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(10,097,931)	(10,097,931)
Balance at December 31, 2010	734,538	32,893,002	—	—	—	—	—	—	—	—	154,124	1	—	(30,614,874)	(30,614,873)
Sale of Series B preferred stock, net of issuance costs of \$302,905	—	—	1,287,525	17,722,436	—	—	—	—	—	—	—	—	—	—	—
Accretion of preferred stock to redemption value	—	2,033,817	—	936,769	—	—	—	—	—	—	—	—	(690,277)	(2,280,309)	(2,970,586)
Distribution of subsidiary	—	—	—	—	—	—	—	—	—	—	—	—	382,850	—	382,850
Issuance of restricted common stock	—	—	—	—	—	—	—	—	—	—	167,690	2	(2)	—	—
Issuance of note receivable from sale of restricted common stock	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	307,429	—	307,429
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(15,296,685)	(15,296,685)
Balance at December 31, 2011	734,538	34,926,819	1,287,525	18,659,205	—	—	—	—	—	—	321,814	3	—	(48,191,868)	(48,191,865)

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**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Preferred Stock and Stockholders' Equity (Deficit)**  
**Period from February 27, 2007 (inception) through December 31, 2013**

	Redeemable Convertible Preferred Stock								Stockholders' Equity (Deficit)						
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		2012 Series X Convertible Preferred Stock		2007 Series X Convertible Preferred Stock	Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	\$0.00001 Par Value	Number of Shares				\$0.00001 Par Value
Accretion of preferred stock to redemption value	—	\$ 2,165,667	—	\$ 1,156,980	—	\$ —	—	\$ —	—	\$ —	—	\$ —	\$(122,341)	\$ (3,200,306)	\$ (3,322,647)
Issuance of restricted common stock	—	—	—	—	—	—	—	—	—	—	30,047	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	122,341	—	122,341
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,195,957)	(8,195,957)
Balance at December 31, 2012	734,538	37,092,486	1,287,525	19,816,185	—	—	—	—	—	—	351,861	3	—	(59,588,131)	(59,588,128)
Issuance of restricted common stock	—	—	—	—	—	—	—	—	—	—	333,215	3	(3)	—	—
Issuance of common stock	—	—	—	—	—	—	—	—	—	—	100,981	1	(1)	—	—
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	8,204	—	5,336	—	5,336
Forfeitures of restricted common stock	—	—	—	—	—	—	—	—	—	—	(3,778)	—	—	—	—
Reclassification of 2012 Series X preferred stock upon modification	—	—	—	—	—	—	25,000	2,486,251	—	—	—	—	—	—	—
Sale of 2012 Series X preferred stock, net of issuance costs of \$42,096	—	—	—	—	—	—	25,000	2,457,904	—	—	—	—	—	—	—
Sale of Series C preferred stock, net of issuance costs of \$1,151,923	—	—	—	—	2,945,742	40,088,465	—	—	—	—	—	—	—	—	—
Conversion of 2012 Series X preferred stock into Series C preferred stock	—	—	—	—	357,143	4,944,155	(50,000)	(4,944,155)	—	—	—	—	—	—	—

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**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
**Period from February 27, 2007 (inception) through December 31, 2013**

	Redeemable Convertible Preferred Stock								Stockholders' Equity (Deficit)						
	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		2012 Series X Convertible Preferred Stock		2007 Series X Convertible Preferred Stock	Common Stock		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	\$0.00001 Par Value	Number of Shares	\$0.00001 Par Value			
Accretion of preferred stock to redemption value	—	\$ 2,274,608	—	\$ 1,440,859	—	\$ 52,170,377	—	\$ —	—	\$ —	—	\$ —	\$ (1,569,091)	\$ (54,316,753)	\$ (55,885,844)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	1,563,759	—	1,563,759
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(13,167,180)	(13,167,180)
Balance at December 31, 2013	734,538	39,367,094	1,287,525	21,257,044	3,302,885	97,202,997	—	—	—	—	790,483	7	—	(127,072,064)	(127,072,057)
Stock-based compensation expense for awards issued with performance-based vesting conditions contingent upon occurrence of Liquidity Event, as defined (unaudited)	—	—	—	—	—	—	—	—	—	—	—	—	67,548	(67,548)	—
Conversion of convertible preferred stock into common stock (unaudited)	(734,538)	(39,367,094)	(1,287,525)	(21,257,044)	(3,302,885)	(97,202,997)	—	—	—	—	6,858,496	69	94,394,093	63,432,973	157,827,135
Pro forma Balance at December 31, 2013 (unaudited)	—	\$ —	—	\$ —	—	\$ —	—	\$ —	—	\$ —	7,648,979	\$ 76	\$94,461,641	\$ (63,706,639)	\$ 30,755,078

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**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Statements of Cash Flows**

	Year Ended December 31,		February 27, 2007 (inception) through December 31, 2013
	2012	2013	2013
<b>Operating activities:</b>			
Net loss	\$ (8,195,957)	\$ (13,167,180)	\$ (63,041,917)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on extinguishment of debt and other liabilities	—	(2,419,766)	(3,735,499)
Depreciation expense	—	1,282	91,421
Amortization of debt issuance costs	16,613	8,544	81,248
Amortization of debt discount and interest expense	1,654,136	751,880	5,159,034
Gain on cancellation of preferred stock future tranche rights	—	—	(653,465)
Issuance of 2007 Series X preferred stock for licensing agreement	—	—	31,800
Stock-based compensation expense	122,341	1,563,759	2,309,252
Changes in operating assets and liabilities:			
Accounts receivable	(3,518)	(49,706)	(135,339)
Prepaid expenses and other current assets	243,511	(166,874)	(710,072)
Other assets	—	(125,345)	(125,345)
Accounts payable and accrued expenses	(1,047,964)	2,271,735	3,616,889
Net cash used in operating activities	<u>(7,210,838)</u>	<u>(11,331,671)</u>	<u>(57,111,993)</u>
<b>Investing activities:</b>			
Purchases of property and equipment	—	(19,732)	(272,792)
Proceeds from maturities of short-term investments	—	1,990,000	13,177,943
Proceeds from sale of short-term investments	1,365,943	—	800,234
Purchases of short-term investments	—	(13,394,944)	(25,383,162)
Net cash (used in) provided by investing activities	<u>1,365,943</u>	<u>(11,424,676)</u>	<u>(11,677,777)</u>
<b>Financing activities:</b>			
Proceeds from issuance of preferred stock	—	41,240,388	83,033,938
Preferred stock issuance costs	—	(1,194,019)	(1,682,007)
Debt issuance costs	(25,157)	—	(76,857)
Initial public offering issuance costs	—	(221,168)	(221,168)
Proceeds from issuance of 2012 Series X preferred stock	2,500,001	2,500,000	5,000,001
Proceeds from issuance of common stock	—	5,336	5,376
Proceeds from issuance of convertible debt	—	—	3,945,715
Net cash provided by financing activities	<u>2,474,844</u>	<u>42,330,537</u>	<u>90,004,998</u>
Increase (decrease) in cash and cash equivalents	<u>(3,370,051)</u>	<u>19,574,190</u>	<u>21,215,228</u>
Cash and cash equivalents at beginning of period	5,011,089	1,641,038	—
Cash and cash equivalents at end of period	<u>\$ 1,641,038</u>	<u>\$ 21,215,228</u>	<u>\$ 21,215,228</u>
<b>Non-cash financing activities:</b>			
Issuance of Series A preferred stock in settlement of convertible notes	\$ —	\$ —	\$ 5,383,000
Accretion of preferred stock to redemption value	\$ 3,322,647	\$ 55,885,844	\$ 66,738,199
Reclassification of 2012 Series X preferred stock from debt to preferred stock	\$ —	\$ 2,486,251	\$ 2,486,251
Conversion of 2012 Series X preferred stock into Series C preferred stock	\$ —	\$ 4,944,155	\$ 4,944,155
Unpaid initial public offering issuance costs	\$ —	\$ 856,970	\$ 856,970
Assets acquired under capital lease	\$ —	\$ 11,916	\$ 11,916
Loss on extinguishment of 2007 Series X preferred stock	\$ —	\$ —	\$ 597,174
Book value of assets transferred in distribution of subsidiary	\$ —	\$ —	\$ 193,114
Book value of liabilities transferred in distribution of subsidiary	\$ —	\$ —	\$ (575,964)
Exchange of convertible debt	\$ —	\$ —	\$ 304,054

See accompanying notes to financial statements.

**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Notes to Financial Statements**  
**December 31, 2013**

**1. Nature of Organization and Operations**

Akebia Therapeutics, Inc. (the “Company”) is a biopharmaceutical company focused on the development of novel proprietary therapeutics based on hypoxia inducible factor (“HIF”) biology and the commercialization of these products for patients with kidney disease. HIF is the primary regulator of the production of red blood cells in the body and a potentially novel mechanism of treating anemia. The Company’s lead product candidate, AKB-6548, is being developed as a once-daily oral therapy that has successfully completed a Phase 2a proof of concept study demonstrating that AKB-6548 can safely and predictably raise hemoglobin levels in patients with anemia secondary to chronic kidney disease (“CKD”) not requiring dialysis. AKB-6548 is currently being studied in a Phase 2b trial in patients with anemia secondary to CKD, who are not dependent on dialysis, with data expected in the fourth quarter of 2014.

The Company’s operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing its technology, identifying potential product candidates and undertaking preclinical and clinical studies. The Company has not generated any product revenues to date, nor is there any assurance of any future product revenues. The Company’s product candidates are subject to long development cycles and there is no assurance the Company will be able to successfully develop, obtain regulatory approval, for or market its product candidates. Accordingly, the Company is considered to be in the development stage as defined by U.S. generally accepted accounting principles (“U.S. GAAP”).

The Company is subject to a number of risks similar to other life science companies in the development stage, including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of any of the Company’s products that are approved and protection of proprietary technology. If the Company does not successfully commercialize any of its products, it will be unable to generate product revenue or achieve profitability. As of December 31, 2012 and December 31, 2013, the Company had a deficit accumulated during the development stage of approximately \$59.6 million and \$127.1 million, respectively.

Unless otherwise indicated, all information in these financial statements gives retrospective effect to the one-hundred-to-one reverse stock split of the Company’s common stock (the “Stock Split”) that was effected on May 10, 2013 (see Note 9).

The Company was incorporated on February 27, 2007, under the laws of the State of Delaware.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The financial statements of the Company are prepared in accordance with US GAAP and stated in U.S. Dollars.

In December 2011, the Company spun out the Company’s programs focused on the treatment of diabetic eye disease and inflammatory bowel disease into Aerpio Therapeutics, Inc. (“Aerpio”), as more fully described in Note 3.

**Unaudited Pro Forma Presentation and Unaudited Pro Forma Net Loss per Share**

On December 19, 2013, the Company’s Board of Directors authorized the management of the Company to file a registration statement with the U.S. Securities and Exchange Commission (“SEC”) for the Company to sell shares of its common stock (the “Common Stock”) to the public. The unaudited pro forma balance sheet and statement of redeemable convertible preferred stock and stockholders’ equity (deficit) as of December 31, 2013

**Akebia Therapeutics, Inc.**  
**(A Development Stage Company)**  
**Notes to Financial Statements**  
**December 31, 2013**

assumes the automatic conversion of all outstanding convertible preferred stock into shares of Common Stock upon the completion of the proposed offering and includes the compensation expense impact related to awards of restricted stock issued with a vesting condition contingent upon the Company's consummation of a Liquidity Event, as defined.

Unaudited pro forma basic and diluted net loss per share was calculated by dividing net loss attributable to common stockholders, excluding the impact of gains (losses) on the extinguishment of preferred stock and accretion of preferred stock, and including the impact of compensation expense associated with awards of restricted stock that contain a performance condition wherein vesting is contingent upon the Company's consummation of a Liquidity Event, as defined, by the pro forma weighted-average number of common shares outstanding. The unaudited pro forma weighted-average number of common shares outstanding was computed after giving effect to the assumed conversion of the redeemable convertible preferred stock into shares of common stock as if such conversion had occurred at the beginning of the period presented, or the date of original issuance, if later and includes the impact of the issuance of restricted stock with a vesting condition contingent upon the Company's consummation of a Liquidity Event, as defined.

**Segment Information**

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing proprietary therapeutics based on HIF biology.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: stock-based compensation expense, fair value of common stock and preferred stock and the Company's other equity instruments, accrued expenses and income taxes.

The Company utilizes significant estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair market value of its common stock as determined by the board of directors contemporaneously at the date such grants were made, with input from management. The fair value of common stock at the grant date was adjusted in connection with the Company's retrospective fair value assessment for financial reporting purposes. The Board of Directors has determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors,

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### **Akebia Therapeutics, Inc. (A Development Stage Company) Notes to Financial Statements December 31, 2013**

including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an initial public offering or sale of the Company.

The Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, *Valuation of Privately-Held Company Equity Securities Issued as Compensation*, to estimate the fair value of its common stock. The methodologies included a probability analysis including both a potential public trading scenario and potential sale scenario. In both scenarios, value is estimated using the guideline public company method. The sale scenario includes an adjustment for a market participant acquisition premium. Value is allocated among the preferred and common shares according to the rights associated with each type of security. Valuation methodologies include estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of a public offering. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

The Company's results can also be affected by economic, political, legislative, regulatory and legal actions. Economic conditions, such as recessionary trends, inflation, interest and monetary exchange rates, government fiscal policies and changes in the prices of research studies, can have a significant effect on operations. While the Company maintains reserves for anticipated liabilities and carries various levels of insurance, the Company could be affected by civil, criminal, regulatory or administrative actions, claims or proceedings.

#### **Cash and Cash Equivalents**

Cash and cash equivalents consist of all cash on hand, deposits and funds invested in short-term investments with original maturities of three months or less at the time of purchase. The Company may maintain balances with its banks in excess of federally insured limits.

#### **Investments**

Management determines the appropriate classification of securities at the time of purchase and reevaluates such designation as of each balance sheet date. Currently, the Company classifies all investments as trading account assets. Investments are generally available for resale, consisting principally of corporate and government debt securities and are stated at fair value. Gains and losses, both realized and unrealized, are included in the caption Interest expense, net within the statements of operations and comprehensive loss. The Company bases the cost of securities sold upon the specific identification method, and includes interest and dividends on securities in interest income.

#### **Grant Income**

Grant income is recognized as earned based on contract work performed. Grant income also includes qualifying therapeutic credits from the U.S. Treasury related to discovery projects.

#### **Research and Development**

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expense consists of (i) employee-related expenses, including salaries, benefits, travel and stock-based compensation expense; (ii) external research and development expenses incurred under arrangements with

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third parties, such as contract research organizations and consultants; (iii) the cost of acquiring, developing and manufacturing clinical study materials; (iv) facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies; and (v) costs associated with preclinical activities and regulatory operations.

The Company enters into consulting, research and other agreements with commercial firms, researchers, universities and others for the provision of goods and services. Under such agreements, the Company may pay for services on a monthly, quarterly, project or other basis. Such arrangements are generally cancellable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to us by the Company's clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company.

#### **Patents**

Costs incurred in connection with the application for and issuances of patents are expensed as incurred.

#### **Organizational Costs**

All organizational costs and start-up costs are expensed as incurred.

#### **Income Taxes**

Income taxes are recorded in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of December 31, 2012 and 2013, the Company does not have any significant uncertain tax positions. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

#### **Stock-Based Compensation**

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock and modifications to existing stock awards, to be recognized in the statements of operations and comprehensive loss based on their fair values. The Company accounts for stock-based awards to non-employees in accordance with FASB ASC Topic 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50"), which requires the fair value of the award to be re-measured at



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fair value until a performance commitment is reached or counterparty performance is complete. The Company's stock-based awards are comprised of stock options, shares of restricted stock and shares of common stock. The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Company uses an estimate of its Common Stock value to determine the fair value of restricted stock awards and common stock awards.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the trading of the Company's common stock and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company is a development stage company in a very early stage of product development with no revenues and the representative group of companies has certain similar characteristics to the Company. The Company believes the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of the Company. The Company performed a sensitivity analysis to determine the impact a 30% increase or decrease in the volatility rate would have on the fair value of each stock-based award, and determined that such a rate change would be immaterial to the calculation of stock-based compensation. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock, which is similar to the Company's peer group.

The Company's stock-based awards are subject to either service or performance based vesting conditions. Compensation expense related to awards to employees with service based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with service based vesting conditions is recognized on a straight-line basis based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term. Compensation expense related to awards to employees with performance based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with performance based vesting conditions is recognized based on the then-current fair value at each financial reporting date prior to the measurement date over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

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The Company is also required to estimate forfeitures at the time of grant, and revise those estimates in the subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

**Fair Value of Financial Instruments**

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC 820"), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments, and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active, or for which all significant inputs are observable, either directly or indirectly.

Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis include short-term investments (see Note 6). The carrying amounts of accounts receivable, accounts payable and accrued expenses approximate their fair values due to their short-term maturities. The rate implicit within the Company's capital lease obligation approximates market interest rates.

**Concentrations of Credit Risk and Off-Balance Sheet Risk**

Cash, investments and accounts receivable are the only financial instruments that potentially subject the Company to concentrations of credit risk. At December 31, 2012 and December 31, 2013, all of the Company's cash was deposited in accounts at two principal financial institutions. The Company maintains its cash with a high quality, accredited financial institution and, accordingly, such funds are subject to minimal credit risk. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

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**Net Loss per Share**

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, preferred stock, stock options and unvested restricted stock are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

**Comprehensive Loss**

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss was equal to net loss for all periods presented.

**Deferred Offering Costs**

Deferred offering costs, which primarily consist of direct incremental legal and accounting fees relating to the Company's initial public offering (IPO), are capitalized. The deferred offering costs will be offset against IPO proceeds upon the consummation of the offering. In the event the offering is terminated or significantly delayed, deferred offering costs will be expensed. Deferred offering costs were \$1,078,138 at December 31, 2013, of which \$856,970 were accrued at December 31, 2013. No amounts were incurred or deferred as of December 31, 2012.

**Equipment**

Equipment is stated at cost, less accumulated depreciation. Assets under capital lease are included in Equipment. Equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally three years. Such costs are periodically reviewed for recoverability when impairment indicators are present. Such indicators include, among other factors, operating losses, unused capacity, market value declines and technological obsolescence. Recorded values of asset groups of equipment that are not expected to be recovered through undiscounted future net cash flows are written down to current fair value, which generally is determined from estimated discounted future net cash flows (assets held for use) or net realizable value (assets held for sale).

The following is the summary of equipment and related accumulated depreciation as of December 31, 2013 and December 31, 2012.

	<u>Useful life</u>	<u>December 31, 2013</u>	<u>December 31, 2012</u>
Computer equipment and software	3	\$ 19,732	\$ —
Office equipment under capital lease	3	11,916	—
		31,648	—
Less accumulated depreciation		(1,282)	—
Net property, plant and equipment		<u>\$ 30,366</u>	<u>\$ —</u>

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Depreciation expense, including expense associated with assets under capital leases, was \$1,282 for the year ended December 31, 2013. There was no depreciation expense recognized during the year ended December 31, 2012.

**Subsequent Events**

The Company evaluates events and transactions occurring subsequent to the date of the financial statements for matters requiring recognition or disclosure in the financial statements. The accompanying financial statements consider events through February 14, 2014, the date on which the financial statements were issued.

**Recent Accounting Pronouncements**

In February 2013, the FASB issued guidance to provide information about the amounts reclassified out of accumulated other comprehensive income, or AOCI, by component. An entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. On January 1, 2013, the Company adopted this standard, which had no impact on the Company's financial position or results of operations.

**3. Distribution of Aerpio**

On December 22, 2011, the Company assigned certain assets and liabilities to a wholly owned subsidiary, Aerpio. The assigned assets and liabilities included all of the Company's fixed assets, the Company's Tie2 activator program, AKB-9778, for diabetic macular edema, the HIF-1 stabilizer program, AKB-4924, for inflammatory bowel disease and contracts, intellectual property, current assets and current liabilities associated with these programs. The Aerpio shares were then distributed to the Company's shareholders as a distribution on the basis of 1 share of Aerpio Series A Preferred Stock for every 35 shares of Akebia Series A Preferred Stock owned, 1 share of Aerpio Series A Preferred Stock for every 100 shares of Akebia Series B Preferred Stock owned, and 1 share of Aerpio Common Stock for every 100 shares of Akebia Common Stock owned.

As of December 22, 2011, the Company assigned the following assets and liabilities to Aerpio at their historical carrying amounts:

Current assets	\$ 30,149
Equipment, net of accumulated depreciation	162,965
Current liabilities	(575,964)
Net gain on distribution of Aerpio, reflected as an increase to additional-paid-in capital	<u>\$(382,850)</u>

The Company has not presented Aerpio as a discontinued operation in the accompanying financial statements given the significance of on-going cash flows between the Company and Aerpio. Under the terms of administrative services agreements, the Company and Aerpio obtain from and provide to each other certain services beginning in 2012, and as outlined below. These agreements are cancellable upon mutual agreement or a sale of either company.

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Below is a summary of the activities included in the statements of operations and comprehensive loss:

Activity	Financial Statement Caption	Year Ended December 31,		February 27, 2007 (inception) through December 30, 2013
		2012	2013	
Reimbursement from Aerpio for Akebia employee costs	Reimbursements from Aerpio	\$ 1,971,246	\$ 1,049,844	\$ 3,021,090
Facility-related charges from Aerpio	General and administrative Operating expenses	177,757	277,923	455,680

Below is a summary of the receivables and payables included in the balance sheet related to Aerpio:

Activity	Financial Statement Caption	2012	2013
Amounts receivable from Aerpio	Accounts receivable	\$ 60,678	\$ 135,339
Amounts payable to Aerpio	Accounts payable	\$ 64,294	\$ 62,735

Prior to distribution on December 22, 2011, the direct revenues and expenses attributable to Aerpio related activities are summarized as follows:

	February 27, 2007 (Inception) through December 31, 2013
Research and development expenses	\$ 8,889,877
General and administrative expenses	251,340
Total operating expenses	(9,141,217)
Grant income	834,603
Loss from Aerpio activities	<u><u>\$ (8,306,614)</u></u>

**4. Investments**

Investments at fair value consist of the following:

	December 31,	
	2012	2013
Certificates of deposit	\$—	\$ 1,330,132
U.S. Government debt securities	—	7,509,369
Corporate debt securities	—	2,501,740
	<u><u>\$—</u></u>	<u><u>\$11,341,241</u></u>

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The estimated fair value of the Company's investment balance at December 31, 2013, by contractual maturity, is as follows:

Due in one year or less	\$ 3,100,430
Due after one year through three years	8,240,811
Total investment securities	<u>\$ 11,341,241</u>

### 5. Accrued Expenses

Accrued expenses are as follows:

	December 31,	
	2012	2013
Professional fees	\$ 55,420	\$ 2,452,067
Accrued bonus	152,293	439,435
Accrued vacation	35,751	109,921
Other	107,786	182,338
Total accrued expenses	<u>\$ 351,250</u>	<u>\$ 3,183,761</u>

### 6. Fair Value of Financial Instruments

The Company utilizes a portfolio management company for the valuation of the majority of its investments. This company is an independent, third-party vendor recognized to be an industry leader with access to market information that obtains or computes fair market values from quoted market prices, pricing for similar securities, recently executed transactions, cash flow models with yield curves and other pricing models. For valuations obtained from the pricing service, the Company performs due diligence to understand how the valuation was calculated or derived, focusing on the valuation technique used and the nature of the inputs.

Based on the fair value hierarchy, the Company classifies its cash equivalents and marketable securities within Level 1 or Level 2. This is because the Company values its cash equivalents and marketable securities using quoted market prices or alternative pricing sources and models utilizing market observable inputs.

Assets measured or disclosed at fair value on a recurring basis as of December 31, 2013 are summarized below:

Assets:	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
Cash and cash equivalents	\$ 21,215,228	\$ —	\$ —	\$ 21,215,228
Certificates of deposit	—	1,330,132	—	1,330,132
U.S. Government debt securities	—	7,509,369	—	7,509,369
Corporate debt securities	—	2,501,740	—	2,501,740
	<u>\$ 21,215,228</u>	<u>\$ 11,341,241</u>	<u>\$ —</u>	<u>\$ 32,556,469</u>

The Company's corporate debt securities are all investment grade.

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Assets measured or disclosed at fair value on a recurring basis as of December 31, 2012 are summarized below:

Assets:	Fair Value Measurements Using			Total
	Level 1	Level 2	Level 3	
Cash and cash equivalents	\$1,641,038	\$ —	\$ —	\$1,641,038
	<u>\$1,641,038</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,641,038</u>

The Company had no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at December 31, 2013 and 2012.

Investment securities are exposed to various risks such as interest rate, market and credit. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is at least reasonably possible that changes in risks in the near term would result in material changes in the fair value of investments.

## 7. Convertible Notes

### 2007 Promissory Notes

In 2007, the Company issued convertible secured promissory notes for aggregate proceeds totaling \$1,350,000 (the "2007 Notes"). The 2007 Notes bore interest at a rate of 12% per annum and were payable at maturity. The 2007 Notes also contained a provision that provided for the automatic settlement with securities of the Company upon completion of a Qualified Financing, as defined in the 2007 Notes, and for the optional settlement with securities of the Company upon the closing of any other financing that did not qualify as a Qualified Financing, as defined in the 2007 Notes, both at 50% of the price per share of the security sold in the financing, among other conversion features. The Company concluded that the settlement of the 2007 Notes in connection with a Qualified Financing was the predominant settlement feature and as a result, accounted for the 2007 Notes as share settled debt. Accordingly, the 2007 Notes were accreted to their redemption value over the expected period to redemption. The 2007 Notes were set to expire during 2007. In anticipation of the sale of Series A Redeemable Convertible Preferred Stock (see Note 8), the maturity dates of the outstanding 2007 Notes were extended to the earlier of the closing of Series A Redeemable Convertible Preferred Stock, or January 31, 2008.

In connection with the issuance of Series A Redeemable Convertible Preferred Stock, in January 2008 (see Note 8), the holders of the 2007 Notes agreed to a modification of the conversion discount from 50% to 20%. On January 23, 2008, all of the outstanding principal and accrued interest thereon of the 2007 Notes were settled through the issuance of 45,228 shares of Series A Redeemable Convertible Preferred Stock (see Note 8). The Company recognized a gain on settlement of the 2007 Notes of \$1,268,180 based on the difference between the aggregate fair value of the Series A Redeemable Convertible Preferred Stock issued upon settlement and the accreted carrying value of the 2007 Notes on January 23, 2008.

### 2008 Promissory Note

In August 2008, a holder of Series A Redeemable Convertible Preferred Stock advanced \$1,200,000 to the Company in the form of a convertible note (the "2008 Note"). The 2008 Note required, among other things, that the Company maintain an amount equal to the outstanding principal balance of the note in either a certificate of

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deposit, interest bearing account or other cash equivalent, approved by the holder, as collateral for the unpaid principal balance. The 2008 Note bore interest equal to all investment earnings on the cash held as collateral and was payable at maturity. The original maturity of the 2008 Note was June 30, 2009. In anticipation of the July 2009 sale of Series A Redeemable Convertible Preferred Stock (see Note 8), the maturity date was extended to July 15, 2009. The 2008 Note was originally convertible into 3,000,000 shares of Series A Redeemable Convertible Preferred Stock in fulfillment of the investor's commitments under the 2008 Milestone Offering, which was part of the January 23, 2008 Series A Redeemable Convertible Preferred Stock issuance. The 2008 Milestone Offering was cancelled in May 2009, effectively removing the conversion feature included in the 2008 Note. In addition, in May 2009, the principal value of the 2008 Note was reduced to \$895,946 upon the issuance of a new convertible promissory note in the principal amount of \$304,054 (see below).

On July 15, 2009, the principal balance and accrued interest thereon of the 2008 Note of \$916,137 was applied towards the holder's purchase of Series A Redeemable Convertible Preferred Stock in the associated round of financing. As a result, the Company issued 22,904 shares of Series A Redeemable Convertible Preferred Stock in settlement of its obligations under the 2008 Note in July 2009. The gain on the settlement of the 2008 Note was \$11,452, based on the difference between the aggregate fair value of the Series A Redeemable Convertible Preferred Stock issued upon settlement and the carrying value of the 2008 Note at the date of settlement.

**2009 Promissory Notes**

In May 2009, the Company issued additional convertible secured promissory notes for aggregate proceeds totaling \$1,395,715. These convertible secured promissory notes have the same terms as the \$304,054 of convertible promissory notes issued in exchange for a portion of the 2008 Note, as discussed above (collectively, the "2009 Notes"). The notes bore interest at a rate of 10% per annum and were payable at maturity. The 2009 Notes also contained a provision that provided for the automatic settlement with securities of the Company upon completion of a Qualified Financing, as defined in the 2009 Notes, at 60% of the price per share of the security sold in the financing. In addition, the 2009 Notes were convertible into shares of the Company's Series A Redeemable Convertible Preferred Stock at the option of the holder at \$40.00 per share. The Company concluded that the settlement of the 2009 Notes in connection with a Qualified Financing was the predominant settlement feature and as a result, accounted for the 2009 Notes as share settled debt. Accordingly, the 2009 Notes were accreted to their redemption value over the expected period to redemption. The maturity date of the 2009 Notes was originally December 31, 2009, but was extendable to December 31, 2010, at the option of the Company, with consent of the lender.

On July 15, 2009, all of the outstanding principal and accrued interest thereon of the 2009 Notes were settled through the issuance of 72,201 shares of Series A Redeemable Convertible Preferred Stock (see Note 8). The Company recognized a gain on settlement of the 2009 Notes of \$36,101 based on the difference between the aggregate fair value of the Series A Redeemable Convertible Preferred Stock issued upon settlement and the accreted carrying value of the 2009 Notes on July 15, 2009.

**8. Redeemable Convertible Preferred Stock**

**Preferred Stock Financings**

**2007 Series X Convertible Preferred Stock**

In September 2007, the Company issued 9,938 shares of 2007 Series X Preferred Stock to The Procter & Gamble Company in consideration for an exclusive worldwide license agreement to certain patents and technology. The value of these shares was charged to research and development expense based on the fair value of the stock at the time of issuance.



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The 2007 Series X Preferred Stock shared ratably with the common stock in liquidation, and at issuance was convertible into common stock at a rate equal to 19.9% of the post-conversion common stock equivalents outstanding. In connection with the issuance of Series A Redeemable Convertible Preferred Stock in January 2008, the 2007 Series X Preferred Stock became convertible into common stock at a rate of 7.25 shares for each share outstanding at the option of the holder, and automatically convertible into common stock on May 1, 2008. The modification of the 2007 Series X Preferred Stock has been treated as an extinguishment. On May 1, 2008, all outstanding shares of 2007 Series X Preferred Stock converted into 72,047 shares of common stock.

**2012 Series X Preferred Stock**

On July 9, 2012, the Company issued 25,000 shares of 2012 Series X Preferred Stock at \$100.00 per share for aggregate proceeds of \$2,500,001. The terms of the 2012 Series X Preferred Stock at issuance provided that the 2012 Series X Preferred Stock were redeemable at a price of \$200.00 per share at the earlier of a Deemed Liquidation Event, as defined, or March 31, 2013. In accordance with the guidance in ASC No. 480, *Distinguishing Liabilities from Equity*, the shares of 2012 Series X Preferred Stock were considered mandatorily redeemable and classified as liabilities upon issuance. The 2012 Series X Preferred Stock were being accreted to the redemption amount over the period from issuance to March 31, 2013.

In March 2013, the Company issued an additional 25,000 shares of 2012 Series X Preferred Stock at \$100.00 per share for aggregate proceeds of \$2,500,001. In addition, the terms of the 2012 Series X were modified to (i) remove the redemption feature, and (ii) add a conversion feature, which provided the 2012 Series X Preferred Stock, unless converted earlier, were convertible upon the earlier of (a) the approval of the holders of at least 60% of the Series X Convertible Preferred Stock, or (b) June 30, 2013 into a number of shares of Series B Redeemable Convertible Preferred Stock determined by dividing \$100.00 per share by the Series X Conversion Price in effect at the time of conversion. The Series X Conversion Price was \$14.00 per share. In addition, the Series X Convertible Preferred Stock was automatically convertible into fully paid non-assessable shares of capital stock of the Company upon the occurrence of a financing which includes (i) the sale of shares of capital stock that are senior or pari passu with the Series B Redeemable Convertible Preferred Stock with gross proceeds to the Company of at least \$10,000,000, or (ii) in the event of a license deal, a financing plus up-front payment from a licensing transaction which results in gross proceeds to the Company of at least \$30,000,000. Each share of Series X Preferred Stock is automatically converted upon closing of the financing into the number of shares of stock issued in the financing equal to the number of shares of Series X Preferred Stock times \$100, divided by the lowest price paid per share by any investor in the financing. Subsequent to the modification in March 2013, as a result of the removal of the mandatory redemption provisions, the shares of 2012 Series X Preferred Stock were reclassified as temporary equity since the 2012 Series X Preferred Stock could be redeemed at the option of the holder upon Deemed Liquidation Events, as defined. The Company has accounted for the amendment to the 2012 Series X Preferred Stock as an extinguishment of the prior security, which was classified as a liability and the issuance of a new preferred stock due to the significance of the modifications to the substantive contractual terms of the preferred stock and the associated fundamental changes to the nature of the preferred stock. The Company recorded a gain of \$2,419,766 in the statement of operations and comprehensive loss for the period ended December 31, 2013 based on the excess of the book value over the fair value of the revised 2012 Series X Convertible Preferred Stock at the date of the modification of \$2,486,251. The fair value of the 2012 Series X Convertible Preferred Stock was determined using a hybrid method, in which one scenario assumed the conversion of preferred shares to common stock in an IPO, and a second scenario allocated value to the preferred shares using the option-pricing method.

Upon the closing of the Series C Redeemable Convertible Preferred Stock financing in May 2013, all of the outstanding shares of 2012 Series X Preferred Stock were converted into 357,143 shares of Series C Redeemable Convertible Preferred Stock.

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**Redeemable Convertible Preferred Stock**

On January 23, 2008, the Company issued 226,500 shares of Series A Redeemable Convertible Preferred Stock at \$40.00 for aggregate proceeds of \$9,060,000, less issuance costs of \$90,453. In connection with the financing, the Company settled all outstanding 2007 Notes, including accrued interest, with 45,228 shares of Series A Redeemable Convertible Preferred Stock which was recorded at fair value of \$1,626,386 (see Note 7). Additionally, the investors in Series A Redeemable Convertible Preferred Stock agreed to purchase 151,000 additional shares at a price of \$40.00 per share upon the achievement of certain defined milestones (the 2008 Milestone Offering), which the Company concluded should be accounted for as a freestanding financial instrument. The Company allocated \$610,040 of the proceeds to the 2008 Milestone Offering based on the fair value at issuance. The 2008 Milestone Offering was cancelled in May 2009. The reduction of the fair value of the 2008 Milestone Offering has been reflected in net loss for the year ended December 31, 2009.

On July 15, 2009, the Company issued 238,955 shares of Series A Redeemable Convertible Preferred Stock at \$40.00 per share for aggregate proceeds of \$9,558,209, less issuance costs of \$44,008. Additionally, the investors in Series A Redeemable Convertible Preferred Stock agreed to purchase 86,850 additional shares at a price of \$40.00 per share upon the achievement of certain defined milestones (the 2009 Milestone Offering), which the Company concluded should be accounted for as a freestanding financial instrument. The Company allocated \$43,425 of the proceeds to the 2009 Milestone Offerings based on the fair value at issuance. The 2009 Milestone Offering was cancelled in July 2010. The reduction of the fair value of the 2009 Milestone Offering has been reflected in net loss for the year ended December 31, 2010.

In connection with the July 15, 2009 issuance, the Company issued an additional 22,904 shares in settlement of the 2008 Note. In addition, the Company settled all outstanding 2009 Notes including accrued interest with 72,201 shares of Series A Redeemable Convertible Preferred Stock. The shares of Series A Redeemable Convertible Preferred Stock issued in exchange of the 2008 Notes and 2009 Notes, were recorded at fair value at the date of issuance of \$904,685 and \$2,851,929, respectively.

On November 4, 2009, the Company issued 3,750 shares of Series A Redeemable Convertible Preferred Stock at \$40.00 per share for aggregate proceeds of \$150,000. Additionally, the investor in the financing agreed to purchase an additional 1,250 shares at a price of \$40.00 as part of the 2009 Milestone Offering. The Company did not allocate any of the proceeds to the additional participant in the 2009 Milestone Offering, since the fair value was immaterial.

On June 7, 2010, the Company issued 125,000 shares of Series A Redeemable Convertible Preferred Stock at \$40.00 per share for aggregate proceeds of \$5,000,000, less issuance costs of \$29,403.

On April 6, 2011, the Company issued 857,142 shares of Series B Redeemable Convertible Preferred Stock at \$14.00 per share for aggregate proceeds of \$11,999,998, less issuance costs of \$293,905. On April 21, 2011, the Company issued 138,954 shares of Series B Redeemable Convertible Preferred Stock at \$14.00 per share for total aggregate proceeds of \$1,945,343. On December 23, 2011, the Company issued 291,429 shares of Series B Redeemable Convertible Preferred Stock at \$14.00 per share for total proceeds of \$4,080,000, less issuance costs of approximately \$9,000.

On May 10, 2013, the Company issued 2,202,887 shares of Series C Redeemable Convertible Preferred Stock at \$14.00 per share for aggregate proceeds of \$30,840,388. In addition, on May 31, 2013, the Company issued additional 742,855 shares of Series C Redeemable Convertible Preferred Stock at \$14.00 per share for aggregate proceeds of \$10,400,000. The issuance costs related to the issuances of Series C Redeemable Convertible Preferred Stock were \$1,151,923.

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**Summary of Redeemable Convertible Preferred Stock and 2012 Series X Preferred Stock**

As of December 31, 2013, the authorized capital stock of the Company included 5,500,636 shares of preferred stock, par value \$0.00001 per share, of which: (i) 734,538 shares have been designated as Series A redeemable convertible preferred stock (Series A Redeemable Convertible Preferred Stock), (ii) 1,287,525 shares have been designated as Series B redeemable convertible preferred stock (Series B Redeemable Convertible Preferred Stock), (iii) 3,428,572 shares have been designated as Series C redeemable convertible preferred stock (Series C Redeemable Convertible Preferred Stock) and (v) 50,001, shares have been designated as Series X convertible preferred stock (Series X Convertible Preferred Stock). There is no outstanding Series X Convertible Preferred Stock as of December 31, 2013. The Series A Redeemable Convertible Preferred Stock, the Series B Redeemable Convertible Preferred Stock and the Series C Redeemable Convertible Preferred Stock are collectively referred to as the Redeemable Convertible Preferred Stock.

**General**

The rights, preferences and privileges of the preferred stock are as follows:

*Voting*

The holders of shares of Redeemable Convertible Preferred Stock are entitled to the number of votes equal to the number of whole shares of common stock into which the shares of the applicable series of Redeemable Convertible Preferred Stock held by such holder are convertible relating to any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company, or by written consents of stockholders in lieu of meetings. Except as provided by law or otherwise, the holders of shares of Redeemable Convertible Preferred Stock vote together with the holders of shares of common stock as a single class.

The affirmative vote or written consent of the holders of shares constituting 50% (the Appropriate Percentage) of the then outstanding shares of Redeemable Convertible Preferred Stock is required in order for the Company to, among other things: (i) liquidate, dissolve or wind-up the business and affairs of the Company or effect any Deemed Liquidation Event, as defined, (ii) amend, alter or repeal any provision of the Company's Certificate of Incorporation or bylaws that adversely affects the powers, preferences or rights of the Redeemable Convertible Preferred Stock, (iii) create or authorize the creation of, or issue or obligate itself to issue shares of, any additional class or series of capital stock or increase the authorized number of shares of any class of Redeemable Convertible Preferred Stock or increase the authorized number of shares of any additional class or series of capital stock, (iv) reclassify, alter or amend any security of the Company which is *pari passu* with or junior to any class of the Redeemable Convertible Preferred Stock with respect to the payment of dividends or rights of redemption if such reclassification, alteration or amendment would render such other security senior to any class of Redeemable Convertible Preferred Stock with respect to any such right, preference or privilege, (v) purchase, redeem, pay or declare any dividend or make any distribution on, any shares of capital stock other than (1) redemptions of or distributions on Redeemable Convertible Preferred Stock as expressly authorized by the certificate of incorporation and (2) dividends or other distributions payable on the Common Stock solely in the form of additional shares of Common Stock, including the conversion of accrued and unpaid dividends on the Series C Redeemable Convertible Preferred Stock into additional shares of Common Stock pursuant to the articles of incorporation or (3) repurchases of stock from former employees, officers, directors, consultants or other persons, who performed services for the Company, in connection with the cessation of such employment or service that are approved by the Board of Directors, (vi) create, or authorize the creation of, or issue, or authorize the issuance of, any debt security, (vii) create or hold capital stock in, any subsidiary that is not wholly owned by

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the Company or sell, transfer or otherwise dispose of any capital stock of any subsidiary of the Company or permits any subsidiary to sell, lease, transfer or exclusively license or otherwise dispose of all or substantially all of the assets of such subsidiary or (viii) increase or decrease the authorized number of directors constituting the Company's Board of Directors.

Additionally, the affirmative vote by holders of at least 75% of the then-outstanding shares of Series C Redeemable Convertible Preferred Stock is required in order to (1) declare or pay any dividend on Series C Redeemable Convertible Preferred Stock, (2) amend, modify or waive the Company's Certificate of Incorporation in a manner that adversely affects the powers, preferences or rights to the Series C Redeemable Convertible Preferred Stock or (3) increase or decrease the number of authorized shares of Series C Redeemable Convertible Preferred Stock. The affirmative vote by holders of 65% of the then outstanding shares of Series B Redeemable Convertible Preferred Stock is required to (1) amend, modify or waive the Company's Certificate of Incorporation in a manner that adversely affects the powers, preferences or rights of the Series B Redeemable Convertible Preferred Stock or (2) increase or decrease the number of authorized shares of Series B Redeemable Convertible Preferred Stock. The affirmative vote of holders of 65% of the then-outstanding shares of Series A Redeemable Convertible Preferred Stock is required to (1) amend, modify or waive the Company's Certificate of Incorporation in a manner that adversely affects the powers, preferences or rights of the Series A Redeemable Convertible Preferred Stock, or (2) increase or decrease the number of authorized shares of Series B Redeemable Convertible Preferred Stock.

The holders of shares of Redeemable Convertible Preferred Stock are entitled to elect six members of the Company's Board of Directors, which is subject to reduction to not less than four directors under certain circumstances. The holders of shares of Common Stock (including any holders of all shares of Redeemable Convertible Preferred Stock on an as converted basis), are entitled to elect three members of the Company's Board of Directors, which is subject to reduction to two directors under certain circumstances.

### *Dividends*

The holders of shares of Redeemable Convertible Preferred Stock are entitled to receive dividends, at a rate of 6% for the Series A Redeemable Convertible Preferred Stock and the Series B Redeemable Convertible Preferred Stock and 8% for the Series C Redeemable Convertible Preferred Stock. Dividends accrue daily (and compound quarterly) whether or not declared and are cumulative. Dividends are payable only if permitted by law and when and if declared by the Board of Directors. The holders of Series X Redeemable Convertible Preferred Stock are not entitled to dividends.

### *Liquidation*

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or upon the occurrence of a Deemed Liquidation Event, as defined, at the election of holders of more than 50% of the shares of Redeemable Convertible Preferred Stock, the holders of shares of Series C Redeemable Convertible Preferred Stock then outstanding are entitled to be paid out, of the assets of the Company available for distribution to stockholders, an amount per share equal to \$28.00, subject to appropriate adjustment, plus an amount equal to 200% of any accrued but unpaid dividends thereon (Series C Liquidation Amount), before any payment is made to the holders of shares of Series B Redeemable Convertible Preferred Stock, holders of shares of Series A Redeemable Convertible Preferred Stock or holders of shares of Common Stock. Next, the holders of shares of Series B Redeemable Convertible Preferred Stock then outstanding are entitled to be paid out of the assets of the Company available for distribution to stockholders, an amount per share equal to \$14.00, per share, subject to appropriate adjustment, plus any accrued but unpaid dividends thereon (Series B Liquidation Amount), before

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any payment is made to the holders of shares of Series A Redeemable Convertible Preferred Stock or holders of shares of Common Stock. Next, the holders of shares of Series A Redeemable Convertible Preferred Stock then outstanding are entitled to be paid, out of the assets of the Company available for distribution to stockholders, an amount per share equal to \$40.00, subject to appropriate adjustment, plus any accrued but unpaid dividends thereon (Series A Liquidation Amount), before any payment is made to the holders of shares of Common Stock. In the event the assets of the Company available for distribution to stockholders are insufficient to permit payment of the full amount to which each shareholder is entitled, holders of shares of capital stock will share ratably in any distribution of the remaining assets of the Company in proportion to the respective amounts which would otherwise be payable under the circumstances in the order of liquidation preference.

After the payment of all preferential amounts required to be paid to the holders of shares of Redeemable Convertible Preferred Stock, the remaining assets of the Company available for distribution to stockholders will be distributed among the holders of shares of Redeemable Convertible Preferred Stock and Common Stock, pro rata based on the number of shares held by each such holder, treating such securities as if they had been converted to common stock immediately prior to such dissolution, liquidation or winding up of the Company.

*Conversion*

Each share of Redeemable Convertible Preferred Stock is convertible at the option of the holder, at any time and from time to time, into fully paid and non-assessable shares of Common Stock. Each share of Series C Redeemable Convertible Preferred Stock is convertible into that number of common shares as is determined by dividing the Series C Accrued Value by the Applicable Conversion Price. The Series C Accrued Value is defined as the Applicable Original Purchase Price (\$14.00 per share for the Series C Redeemable Convertible Preferred Stock as of December 31, 2013, subject to adjustment) plus accrued but unpaid dividends. Each share of Series B Redeemable Convertible Preferred Stock and Series A Redeemable Convertible Preferred Stock is convertible into that number of common shares as is determined by dividing the Applicable Original Purchase Price of such share (\$14.00 per share for the Series B Redeemable Convertible Preferred Stock and \$40.00 per share for the Series A Redeemable Convertible Preferred Stock, as of December 31, 2013, subject to adjustment) by the Applicable Conversion Price (\$14.00 per share for all Redeemable Convertible Preferred Shares, as of December 31, 2013). The Applicable Conversion Price is subject to adjustment in the future upon the occurrence of certain events.

Each share of Redeemable Convertible Preferred Stock is automatically convertible into fully paid and non-assessable shares of common stock upon either: (i) the closing of the sale of shares of the Company's common stock to the public in an underwritten public offering resulting in at least \$40,000,000 of gross proceeds to the Company, or (ii) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of shares constituting 65% of the then outstanding shares of either Series C Redeemable Convertible Preferred Stock, Series B Redeemable Convertible Preferred Stock or Series A Redeemable Convertible Preferred Stock, respectively, voting as a separate class.

The Company evaluated each series of its preferred stock and determined that each individual series is considered an equity host under ASC No. 815, *Derivatives and Hedging* (ASC 815). In making this determination, the Company's analysis followed the whole instrument approach, which compares an individual feature against the entire preferred stock instrument which includes that feature. The Company's analysis was based on a consideration of the economic characteristics and risks of each series of preferred stock. More specifically, the Company evaluated all of the stated and implied substantive terms and features, including: (i) whether the preferred stock included redemption features, (ii) how and when any redemption features could be exercised, (iii) whether the holders of preferred stock were entitled to dividends, (iv) the voting rights of the

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preferred stock and (v) the existence and nature of any conversion rights. As a result of the Company's conclusion that the preferred stock represents an equity host, the conversion feature of all series of preferred stock is considered to be clearly and closely related to the associated preferred stock host instrument. Accordingly, the conversion feature of all series of preferred stock is not considered an embedded derivative that requires bifurcation.

The Company accounts for potentially beneficial conversion features under ASC No. 470-20, *Debt with Conversion and Other Options* (ASC 470-20). At the time of each of the issuances of Redeemable Convertible Preferred Stock and the Series X Convertible Preferred Stock, the Company's Common Stock (or Series B Redeemable Convertible Preferred Stock in the case of the Series X Convertible Preferred Stock) into which each series of the Company's preferred stock is convertible had an estimated fair value less than the effective conversion prices of the convertible preferred stock. Therefore, there was no intrinsic value on the respective commitment dates.

*Redemption*

The Redeemable Convertible Preferred Stock shall be redeemed by the Company at a price equal to the greater of (i) the Applicable Accrued Value or (ii) the fair market value per share, in three annual installments commencing not more than 60 days following receipt by notice, at any time after July 16, 2015, from holders of more than 50% of the shares of Redeemable Convertible Preferred Stock then outstanding. For the Series C Redeemable Convertible Preferred Stock, the Series B Redeemable Convertible Preferred Stock and the Series A Redeemable Convertible Preferred Stock, the Applicable Accrued Value is equal to the Series C Liquidation Amount, the Series B Liquidation Amount and the Series A Liquidation Amount, respectively. With the exception of the Series B Redeemable Convertible Preferred Stock at December 31, 2013, the Applicable Accrued Value has exceeded each series' respective fair market value for all periods presented. In accordance with the guidance in ASC No. 480, *Distinguishing Liabilities from Equity* (ASC 480), shares of Redeemable Convertible Preferred Stock are classified outside of permanent stockholders' deficit. The Company has elected to recognize changes in redemption value immediately as they occur through adjustments to the carrying amounts of the instruments at the end of each reporting period. Therefore, the Series C Redeemable Convertible Preferred Stock, the Series B Redeemable Convertible Preferred Stock and the Series A Redeemable Convertible Preferred Stock are carried at their respective redemption values. As of December 31, 2013, the redemption values of Series C Redeemable Convertible Preferred Stock and the Series A Redeemable Convertible Preferred Stock are equal to their respective liquidation preferences. As of December 31, 2013, the redemption value of the Series B Redeemable Convertible Preferred Stock is not equal to the liquidation preference as a result of its fair value exceeding its Applicable Accrued Value. The fair value of the Redeemable Convertible Preferred Stock are based upon the probability-weighted expected returns method (PWERM), which is a level 3 fair value measure. Under PWERM, the values of various equity securities are estimated upon an analysis of future values of the Company, assuming various outcomes. Share value is based upon the probability-weighted present value of expected future investment returns, considering each of the possible future outcomes available to the Company, as well as the rights of each share class. The three scenarios considered included IPO, sale of the Company, and liquidation of the Company's assets.

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**Extinguishments of Preferred Stock**

In connection with the issuance of the Series A Redeemable Convertible Preferred Stock on January 23, 2008, certain rights, preferences and privileges for the outstanding 2007 Series X Convertible Preferred Stock were modified. More specifically, the conversion feature was modified to fix the conversion of each share of 2007 Series X Convertible Preferred Stock into 7.25 shares of common stock. In addition, the conversion feature was modified to include an automatic conversion upon the earlier of (i) a Deemed Liquidation Event, as defined, or (ii) May 1, 2008.

The Company has accounted for the amendment to the rights, preferences and privileges of the 2007 Series X Convertible Preferred Stock as an extinguishment of the old preferred stock and issuance of new preferred stock due to the significance of the modifications to the substantive contractual terms of the preferred stock and the associated fundamental changes to the nature of the preferred stock. Accordingly, the Company recorded a loss of \$597,174 within stockholders' deficit equal to the difference between the fair value of the new shares of preferred stock issued and the carrying amount of the old shares of preferred stock extinguished. The loss on extinguishment is reflected as an adjustment to the net loss available to common stockholders in accordance with ASC No. 260, *Earnings per Share* (ASC 260). The fair value of the 2007 Series X Convertible Preferred Stock was determined primarily based on the underlying value of the common stock to be received upon conversion of the 2007 Series X Convertible Preferred Stock.

**9. Stockholders' Equity**

As of December 31, 2013, the authorized capital stock of the Company included 8,400,000 shares of common stock, par value \$0.00001 per share.

On May 10, 2013, the Company affected a one hundred-for-one reverse stock split. Unless otherwise indicated, all share data and per share amounts in these financial statements have been retroactively adjusted to reflect the reverse stock split.

**General**

The voting, dividend and liquidation rights of the holders of shares of Common Stock are subject to and qualified by the rights, powers and preferences of the holders of shares of Redeemable Convertible Preferred Stock. The Common Stock has the following characteristics:

*Voting*

The holders of shares of Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders and written actions in lieu of meetings. Notwithstanding the foregoing, except as otherwise required by law, holders of shares of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation of pursuant to General Corporation Law.

*Dividends*

The holders of shares of Common Stock are entitled to receive dividends, if and when declared by the Board of Directors. The Company may not declare or pay any cash dividends to the holders of Common Stock unless, in addition to obtaining any necessary consents, dividends are paid on each series of Redeemable Convertible Preferred Stock in accordance with their respective terms. As of December 31, 2013, no dividends have been declared or paid to the holders of Common Stock since the inception of the Company.

*Liquidation*

After payment to the holders of shares of Redeemable Convertible Preferred Stock of their liquidation preferences, the holders of Common Stock are entitled to share ratably in the Company's assets available for distribution to stockholders, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company.

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**Reserved for Future Issuance**

As of December 31, 2012 and December 31, 2013 based on the authorized shares for each series, the Company has reserved the following shares of Common Stock for future issuance:

	<b>December 31, 2012</b>	<b>December 31, 2013</b>
Conversion of Series A Redeemable Convertible Preferred Stock	2,098,680	2,098,680
Conversion of Series B Redeemable Convertible Preferred Stock	1,642,857	1,287,525
Conversion of Series C Redeemable Convertible Preferred Stock	—	3,597,978
Options to purchase common stock	279,753	715,085
Shares available for future issuance	555,529	88,633
Total	<u>4,576,819</u>	<u>7,787,901</u>

**10. Income Taxes**

There was no current or deferred income tax expense or benefit for the years ended December 31, 2013 and 2012, due to the Company's net losses and increases in its deferred tax asset valuation allowance.

The U.S. components of loss before income taxes, and a reconciliation of the statutory federal income tax with the provision for income taxes, follow:

	<b>Year Ended December 31,</b>	
	<b>2012</b>	<b>2013</b>
Federal tax at statutory rate	34.0%	34.0%
State and local tax at statutory rate	0.7	0.8
Research and development tax credits	0.0	4.2
Disqualified interest expense	(7.0)	(1.9)
Cancellation of debt income	0.0	6.2
Equity compensation	(0.5)	(2.6)
Change in valuation allowance	(27.2)	(40.7)
Effective tax rate	<u>— %</u>	<u>— %</u>

The Company's income tax provision was computed based on the federal statutory rate and the average state statutory rates, net of the related federal benefit.



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Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31, 2012	December 31, 2013
Deferred tax assets:		
Net operating loss carry-forwards	\$ 13,074,606	\$ 17,916,817
Intangible assets	660,635	602,784
Research and development credit carry-forwards	1,261,955	1,821,403
Accrued expenses	76,586	189,648
Other	14,932	24,371
Deferred tax assets	<u>15,088,714</u>	<u>20,555,023</u>
Deferred tax liabilities:		
Accumulated depreciation	—	925
Stock-based compensation	—	107,556
Deferred tax liabilities	<u>—</u>	<u>108,481</u>
Less: valuation allowance	<u>(15,088,714)</u>	<u>(20,446,542)</u>
Net deferred tax asset	<u>\$ —</u>	<u>\$ —</u>

When realization of the deferred tax asset is more likely than not to occur, the benefit related to the deductible temporary differences attributable to operations is recognized as a reduction of income tax expense. Valuation allowances are provided against deferred tax assets when, based on all available evidence, it is considered more likely than not that some portion or all of the recorded deferred tax assets will not be realized in future periods. The Company cannot be certain that future taxable income will be sufficient to realize its deferred tax assets, and accordingly a full valuation allowance has been provided on its deferred tax assets. The Company continues to maintain the underlying tax benefits to offset future taxable income, and to monitor the need for a valuation allowance based on the profitability of its future operations.

At December 31, 2012 and December 31, 2013, the Company has approximately, \$1,443,000 (after amortization of \$524,700) and \$1,312,000 (after amortization of \$656,000), respectively, of start-up expenses capitalized for income tax purposes with amortization available to offset future federal, state and local income tax. Additionally, at, December 31, 2012 and December 31, 2013, the Company has approximately, \$37,673,000 and \$51,620,000, respectively, of net operating loss (NOL) carry-forwards, and \$1,261,000 and \$1,821,000, respectively, of research and development tax credit carry-forwards. The NOL and research and development tax credit carry-forwards begin to expire in 2027, and will be utilized for tax purposes at such time the Company generates taxable income. The NOL and research and development tax credit carry-forwards may be limited in certain circumstances, including ownership changes.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carry-forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carry-forwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state

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provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed several financings since its inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code, or could result in a change in control in the future. If any of the financings meet the definition of a change in control under Sections 382 and 383 of the Internal Revenue Code, it is possible that a substantial portion of the NOL's and credit carry-forwards could be limited.

Prior to legislation enacted in January 2013, the research and development tax credit was not in place for the 2012 tax year. Accordingly, the Company has not recorded a deferred tax asset for the 2012 research and development tax credit at December 31, 2012. For applicable years, the Company generated research credits but has not conducted a study to document its qualified activities. Such a study may result in an adjustment to the Company's research and development credit carry-forwards; however, until a study is completed and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the deferred tax asset established for the research and development credit carry-forwards and the valuation allowance.

As of December 31, 2012 and December 31, 2013, the Company had no accrued uncertain tax positions or associated interest or penalties and no amounts have been recognized in the Company's consolidated statements of operations.

The Company files income tax returns in the US federal jurisdiction, and various state jurisdictions. The Company's 2009 to 2012 tax years remain open and subject to examination by federal and state taxing authorities.

#### **11. Commitments and Contingencies**

In December 2013, the Company entered into a three-year lease for 6,837 square feet of office space in Cambridge, Massachusetts. The lease has monthly lease payments of approximately \$31,000 for the first twelve months, with annual rent escalation thereafter, and provides a rent abatement of approximately \$31,000 for the first full calendar month of the lease term. The lease term commences and rental payments begin in January 2014. The Company will record a deferred lease obligation in 2014 which will represent the cumulative difference between actual facility lease payments and lease expense recognized ratably over the lease period. The Company did not have rent expense associated with this lease in 2013.

The Company leases office equipment under a three year capital lease with payments commencing in 2014.

At December 31, 2013, the Company's future minimum payments required under these leases are as follows:

	<u>Operating lease</u>	<u>Capital lease</u>	<u>Total</u>
2014	\$ 344,699	\$ 3,850	\$ 348,549
2015	382,872	4,200	387,072
2016	389,709	4,200	393,909
2017	—	350	350
<b>Total</b>	<u>\$ 1,117,280</u>	<u>12,600</u>	<u>\$ 1,129,880</u>
Less amount representing interest		684	
<b>Present value of minimum lease payments at December 31, 2013</b>		<u>\$ 11,916</u>	

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The Company contracts with various organizations to conduct research and development activities with remaining contract costs to the Company of \$737,030 and \$4,477,081 at December 31, 2012 and December 31, 2013, respectively. The scope of the services under the research and development contracts can be modified and the contracts cancelled by either party upon written notice.

## 12. Stock-Based Compensation

In connection with the sale of the Series A and Series B Redeemable Convertible Preferred Stock, the Company approved the creation of an equity incentive plan. There are 803,718 shares of the Company's Common Stock that are reserved for issuance under the plan at December 31, 2013. The plan allows for the grant of incentive stock options and non-qualified stock options to purchase common stock or stock bonuses, or restricted stock awards for management and certain persons performing services or who have performed services in the past for the Company.

### Stock Options

The options granted to directors and non-employees vest over periods of between 12 and 48 months. For employees with less than one year's worth of service, options vest in installments of (i) 25% at the one year anniversary and (ii) in either 36 equal monthly or 12 equal quarterly installments beginning in the thirteenth month after the initial Vesting Commencement Date (as defined), subject to the employee's continuous service with the Company. Options granted to other employees vest in 48 equal monthly installments after the initial Vesting Commencement Date (as defined), subject to the employee's continuous service with the Company. Options generally expire ten years after the date of grant.

The assumptions used in the Black-Scholes option pricing model to estimate the grant date fair value of options granted to employees are as follows:

	December 31,	
	2012	2013
Risk-free interest rate	0.95%	1.71% — 2.03%
Dividend yield	0.00%	0.00%
Volatility	73.00%	75.00% — 79.00%
Expected term (years)	6.25	6.25

The weighted-average fair values of options granted to employees are as follows:

Period	Weighted-Average Fair Value of Options Granted
2013	\$ 6.80
2012	\$ 0.57
2011	\$ 1.32
2010	\$ 2.66
2009	\$ 10.45
2008	\$ 7.51

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The following table summarizes the Company's stock option activity:

	Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Life (in years)	Aggregate Intrinsic Value (a)
Outstanding, January 1, 2008	—	\$ —		
Granted	103,643	1.50		
Exercised	—	—		
Expired/cancelled	—	—		
Outstanding, December 31, 2008	103,643	\$ 1.50		
Granted	46,149	1.50		
Exercised	—	—		
Expired/cancelled	(900)	1.50		
Outstanding, December 31, 2009	148,892	\$ 1.50		
Granted	66,080	1.50		
Exercised	—	—		
Expired/cancelled	—	—		
Outstanding, December 31, 2010	214,972	\$ 1.50		
Granted	24,330	1.50		
Exercised	—	—		
Expired/cancelled	—	—		
Outstanding, December 31, 2011	239,302	\$ 1.50		
Granted	40,451	1.50		
Exercised	—	—		
Expired/cancelled	—	—		
Outstanding, December 31, 2012	279,753	\$ 1.50		
Granted	526,347	1.86		
Exercised	(8,204)	1.50		
Forfeited	(4,608)	1.50		
Expired/cancelled	(78,203)	1.50		
Outstanding, December 31, 2013	715,085	\$ 1.77	8.79	\$8,025,417
Options exercisable, December 31, 2013	164,742	\$ 1.50	5.87	\$1,892,994
Expected to vest, December 31, 2013	550,333	\$ 1.85	9.66	\$6,123,713

As of December 31, 2013, there was approximately \$3,400,000 of unrecognized compensation cost related to stock options, which is expected to be recognized over a weighted average period of 2.3 years.

During 2011, all outstanding stock options granted prior to the issuance of the Series B Redeemable Convertible Preferred Stock were amended to increase the number of option shares from 76,629 to 214,972, and reduce the exercise price per share of each outstanding option from \$4.00 to \$1.50. The increased option shares resulting from the modification were vested in the same proportion as the pre-modification option shares. The fair value of the outstanding options was compared pre- and post-modification, resulting in an incremental fair value of approximately \$93,000 to be recognized as additional compensation cost over the remaining requisite service period.

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During November 2012, outstanding stock options granted to certain employees transferred to Aerpio were modified to allow these former employees to continue to vest in their awards. Because the employees were transferred to Aerpio, the employees were not expected to vest in the original award under its terms, the Company reversed approximately \$62,000 in previously recognized compensation cost in November 2012. The Company recognized the fair value of the new modified award over the requisite service period. However, no substantive future services will be provided to the Company. Accordingly, the Company has accounted for the modification as a severance arrangement with no future service requirement, and has immediately expensed the full fair value of the modified award in 2012, resulting in incremental compensation cost of approximately \$10,000.

A single employee was subsequently transferred to Aerpio in September 2013, with a similar modification. The fair value of the new modified award was expensed in 2013, resulting in incremental compensation cost of approximately \$50,000.

*Restricted Stock*

On June 15, 2011, March 26, 2010 and October 15, 2009, certain employees of the Company purchased 145,404, 10,603 and 31,474 shares, respectively of common stock at a purchase price of \$1.50, \$4.00 and \$4.00 per share, respectively, under the terms of a restricted stock award. These shares were purchased in exchange for promissory notes (the "Promissory Notes"). The shares vest ratably over 48 equal monthly installments beginning on the initial Vesting Commencement Date (as defined), subject to the employee's continuous service with the Company. The Company may purchase all of the unvested shares following the employee's termination at the original purchase price. 173,544 and 125,438 shares were vested at December 31, 2013 and December 31, 2012, respectively. The Promissory Notes accrue interest at the rate of 6% per annum, and are repayable at the earlier of (a) an initial public offering; (b) the sale of the Company or substantially all of its assets; (c) the termination of the employee; or (d) five years from origination. The Promissory Notes are partially collateralized by the assets of the employee.

The Company has accounted for the Promissory Notes as non-recourse in their entirety since the Promissory Notes are not aligned with a corresponding percentage of the underlying shares and the recourse provisions are not substantive as the Company generally does not intend to pursue collection on the recourse portion of the Promissory Notes. Accordingly, the non-recourse notes received by the Company as consideration for the issuance of the restricted stock has been considered a stock option for accounting purposes as the substance is similar to the grant of an option since the employee generally will relinquish the stock in lieu of repaying the Promissory Note.

The fair value of the restricted stock granted to employees in exchange for a Promissory Note is estimated on the grant date using the Black-Scholes option pricing model. The exercise price is the principal due on the Promissory Note. The stated interest rate of the Promissory Notes is reflected as the dividend yield. The fair value of the award is recognized over the requisite service period (not the term of the Promissory Note) through a charge to compensation cost. The maturity date of the Promissory Notes reflect the legal term for purposes of valuing the award. The grant date fair value was estimated using the following assumptions:

	December 31,	
	2012	2013
Risk-free interest rate	0.95%	1.71%
Dividend yield	6.00%	3.00%
Volatility	73.00%	79.00%
Expected term (in years)	5	5

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On May 9, June 6 and June 15, 2013, the terms of the Promissory Notes were amended to (i) reduce the principal owed, and (ii) reduce the interest rate from 6% per annum to 3% per annum, and (iii) increase the term of the note to ten years from the modification date. The fair value of the outstanding awards was compared pre- and post-modification, resulting in an incremental fair value of \$117,000 to be recognized as additional compensation cost over the remaining requisite service period. The Company further reduced the principal owed under the Promissory Note for an employee in 2014.

The Company also grants restricted stock awards to employees and non-employees without related promissory notes. Restricted stock awards without promissory notes generally vest in installments of (i) 25% at the one year anniversary and (ii) in either 36 equal monthly or 12 equal quarterly installments beginning in the thirteenth month after the initial Vesting Commencement Date (as defined), subject to the employee's continuous service with the Company.

On December 23, 2013, the Company issued 257,271 shares of restricted stock to employees and 45,181 shares of restricted stock to non-employees at a grant date fair value of \$12.99 per share. The awards of restricted stock contain a performance condition wherein vesting is contingent upon the Company's consummation of a Liquidity Event, as defined, prior to the fifth anniversary of the date of grant. Certain of the awards of restricted stock have a requisite service period that was complete upon grant. The remainder of the awards of restricted stock have a requisite service period of four years whereby the award vests 25% on the one year anniversary of the Vesting Commencement Date (as defined), then ratably on the first day of each calendar quarter for 12 quarters, subject to continuous service by the individual and achievement of the performance target. Due to the nature of the performance condition, recognition of compensation cost has been deferred until the occurrence of a Liquidity Event, as defined.

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A summary of the Company's restricted stock activity is as follows:

	Shares	Weighted-Average Grant Date Fair Value
Unvested balance, January 1, 2008	—	\$ —
Granted	—	—
Vested	—	—
Forfeited	—	—
Unvested balance, December 31, 2008	—	\$ —
Granted*	31,474	7.14
Vested	—	—
Forfeited	—	—
Unvested balance, December 31, 2009	31,474	\$ 7.14
Granted*	10,603	1.63
Vested	(10,060)	7.14
Forfeited	—	—
Unvested balance, December 31, 2010	32,017	\$ 5.32
Granted*	145,404	0.83
Vested	(68,508)	1.61
Forfeited	—	—
Unvested balance, December 31, 2011	108,913	\$ 1.66
Granted**	30,047	1.00
Vested	(46,870)	1.93
Forfeited	—	—
Unvested balance, December 31, 2012	92,090	\$ 1.30
Granted**	333,215	11.93
Vested	(62,841)	1.68
Forfeited	(3,778)	0.83
Unvested balance, December 31, 2013	358,686	\$ 11.19

\* Grants of restricted stock awards with corresponding promissory notes; grant date fair value is estimated using the Black-Scholes option pricing model.

\*\* Grants of restricted stock awards; grant date fair value is based on the estimated value of the Company's Common Stock.

As of December 31, 2013, there was approximately \$78,000 of unrecognized compensation cost related to restricted stock grants with only service based vesting conditions, which is expected to be recognized over a weighted average period of 1.8 years. Additionally, as of December 31, 2013, there was approximately \$3,929,000 of unrecognized compensation cost related to the restricted stock awards granted on December 23, 2013 with a performance condition, which will be recognized commencing upon the occurrence of a Liquidity Event, as defined.

#### Stock Awards

In connection with the termination of a former employee in September 2013, the Company granted the former employee stock awards totaling 40,551 shares in September 2013 and 60,430 shares in December 2013 of

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Common Stock, at a fair value of \$6.60 per share and \$12.99 per share, respectively. The fair values of the awards are based on the estimated fair value of the Company's Common Stock at the date of grant. Accordingly, compensation cost was recognized in full on the date of grant. The associated common shares immediately vested, and were not subject to any other restriction. Accordingly, compensation cost was recognized in full on the date of grant. Total compensation cost of approximately \$1,053,000 was recognized during the year ended December 31, 2013 related to these awards.

*Compensation Expense Summary*

The Company has recognized the following compensation cost related to share-based awards:

<u>Year Ended</u>	<u>Research and Development</u>	<u>General and Administrative</u>	<u>Total</u>
2013	\$ 110,686	\$ 1,453,073	\$ 1,563,759
2012	52,768	69,573	122,341
2011	175,418	132,011	307,429
2010	93,489	75,782	169,271
2009	57,234	47,503	104,737
2008	18,388	23,327	41,715
Total	<u>\$ 507,983</u>	<u>\$ 1,801,269</u>	<u>\$ 2,309,252</u>

**13. Employee Retirement Plan**

During 2008, the Company established a retirement plan (the Plan) authorized by Section 401(k) of the Internal Revenue Code. In accordance with the Plan, all employees who have attained the age of 21 are eligible to participate in the Plan as of the first Entry Date, as defined, following their date of employment. Each employee can contribute a percentage of compensation up to a maximum of the statutory limits per year. Company contributions are discretionary, and no contributions were made during 2012 or 2013.

**14. Employee Bonus Plan**

The Company maintains a discretionary bonus plan for certain employees of the Company. Accrued bonuses under the plan were \$152,293 and \$439,435 at December 31, 2012 and 2013, respectively. These amounts are recorded as a component of Accrued expenses in the accompanying balance sheets. During the year-ended December 31, 2013 and 2012, the Company recognized \$289,017 and \$385,278 of bonus expense, respectively.



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**15. Net Loss per Share**

The following table presents the calculation of basic and diluted net loss per share applicable to common stockholders:

	<u>Year Ended December 31,</u>		<u>February 27,</u>
	<u>2012</u>	<u>2013</u>	<u>(inception)</u> <u>through</u> <u>December 31,</u> <u>2013</u>
<b>Numerator:</b>			
Net loss	\$ (8,195,957)	(13,167,180)	\$ (63,041,917)
Accretion on preferred stock	(3,322,647)	(55,885,844)	(66,738,199)
Loss on extinguishment of preferred stock	—	—	(597,174)
Net loss applicable to common stockholders	<u>\$ (11,518,604)</u>	<u>\$ (69,053,024)</u>	<u>\$ (130,377,290)</u>
<b>Denominator:</b>			
Weighted-average number of common shares—basic and diluted	236,633	310,858	154,875
Net loss per share applicable to common stockholders—basic and diluted	<u>\$ (48.68)</u>	<u>\$ (222.14)</u>	<u>\$ (841.82)</u>

The amounts in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	<u>Year Ended December 31,</u>		<u>February 27,</u>
	<u>2012</u>	<u>2013</u>	<u>(inception)</u> <u>through</u> <u>December 31,</u> <u>2013</u>
Preferred stock	3,386,202	6,858,496	6,858,496
Outstanding stock options	279,753	715,085	715,085
Unvested restricted stock	92,090	358,686	358,686
Total	<u>3,758,045</u>	<u>7,932,267</u>	<u>7,932,267</u>

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The following table presents the calculation of basic and diluted pro forma net loss per share applicable to common stockholders (see Note 2 for additional information) (unaudited):

	<u>Year Ended December 31, 2013</u> (unaudited)
Numerator:	
Net loss applicable to common stockholders	\$ (69,053,024)
Accretion on preferred stock	55,885,844
Stock-based compensation expense for awards issued with performance-based vesting condition contingent upon occurrence of Liquidity Event, as defined	(136,974)
Pro forma net loss applicable to common stockholders	<u>\$ (13,304,154)</u>
Denominator:	
Weighted-average number of common shares used in net loss per share applicable to common stockholders-basic and diluted	310,858
Pro forma adjustment to reflect assumed conversion of preferred stock to occur upon consummation of the initial public offering	5,479,030
Pro forma adjustment to reflect shares issued associated with awards that contain performance-based vesting condition contingent upon occurrence of Liquidity Event, as defined	128
Pro forma weighted-average number of common shares used in pro forma net loss per share applicable to common stockholders-basic and diluted	<u>5,790,016</u>
Pro forma net loss per share applicable to common stockholders-basic and diluted	<u>\$ (2.30)</u>



Through and including \_\_\_\_\_, 2014 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

**Part II**  
**Information Not Required in Prospectus**

**Item 13. Other Expenses of Issuance and Distribution**

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of common stock being registered. All amounts are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and NASDAQ listing fee.

<u>Item</u>	<u>Amount to be paid</u>
SEC registration fee	\$ 9,660
FINRA filing fee	11,109
NASDAQ listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer Agent fees and expenses	*
Miscellaneous expenses	*
<b>Total</b>	<b>\$ *</b>

\* To be provided by amendment.

**Item 14. Indemnification of Directors and Officers**

Section 145 of the General Corporation Law of the State of Delaware provides as follows:

A corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interest of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful.

A corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the

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extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the Delaware General Corporation Law, we have included in our certificate of incorporation a provision to eliminate the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors, subject to certain exceptions. In addition, our certificate of incorporation and bylaws provide that we are required to indemnify our officers and directors under certain circumstances, including those circumstances in which indemnification would otherwise be discretionary, and we are required to advance expenses to our officers and directors as incurred in connection with proceedings against them for which they may be indemnified.

We intend to enter into indemnification agreements with our directors and officers. These agreements will provide broader indemnity rights than those provided under the Delaware General Corporation Law and our certificate of incorporation. The indemnification agreements are not intended to deny or otherwise limit third-party or derivative suits against us or our directors or officers, but to the extent a director or officer were entitled to indemnity or contribution under the indemnification agreement, the financial burden of a third-party suit would be borne by us, and we would not benefit from derivative recoveries against the director or officer. Such recoveries would accrue to our benefit but would be offset by our obligations to the director or officer under the indemnification agreement.

The underwriting agreement provides that the underwriters are obligated, under certain circumstances, to indemnify our directors, officers and controlling persons against certain liabilities, including liabilities under the Securities Act. Reference is made to the form of underwriting agreement filed as Exhibit 1.1 hereto.

We maintain directors' and officers' liability insurance for the benefit of our directors and officers.

### **Item 15. Recent Sales of Unregistered Securities**

In the three years preceding the filing of this registration statement, we have issued the following securities that were not registered under the Securities Act.

#### **(a) Sales of Capital Stock**

In June 2010, we issued and sold an aggregate of 125,000 shares of Series A preferred stock at a price per share of \$40.00 for total consideration of \$5 million to 15 investors.

In April 2011 and December 2011, we issued and sold an aggregate of 1,287,524 shares of Series B preferred stock at a price per share of \$14.00 for total consideration of \$18,025,341 to 23 investors.

In July 2012 and March 2013, we issued and sold an aggregate of 50,000 shares of our Series X preferred stock at a price per share of \$100.00 for total consideration of \$5,000,002 to 27 investors.

In May 2013, we issued an aggregate of 357,143 shares of Series C preferred stock at an exchange rate of 7.14286 shares of Series C preferred stock for every share of Series X preferred stock.

In May 2013, we issued and sold an aggregate of 2,945,742 shares of our Series C preferred stock at a price per share of \$14.00 for total consideration of \$41,240,388 to 37 investors.

No underwriters were involved in the foregoing sales and exchanges of securities. The securities issued for cash consideration described in this section (a) of Item 15 were issued to third parties in reliance upon, (i) with

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respect to the Series A preferred stock, Series X preferred stock and the 2,945,742 shares of Series C preferred stock, the exemption from the registration requirements of the Securities Act, as set forth in Section 4(2) under the Securities Act; and (ii) with respect to the shares of Series B preferred stock, pursuant to Regulation D promulgated under the Securities Act, in each case related to transactions by an issuer not involving any public offering. The 357,143 shares of Series C preferred stock issued in exchange for Series X preferred stock described in this section (a) of Item 15 were issued in reliance upon Section 3(a)(9) of the Securities Act. All purchasers of preferred stock described above represented to us in connection with their purchase that they were accredited investors or sophisticated investors with such knowledge and experience in financial matters as to be able to evaluate the merits and risks of an investment in such shares. The purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement of an available exemption from such registration.

### **(b) Grants and Exercises of Stock Options**

From January 1, 2010, through February 13, 2014, we granted options to purchase a total of 657,208 shares of our common stock to employees and non-employees, at a weighted-average price of \$1.79 per share. During the same period, we issued 8,204 shares of common stock upon the exercise of options to purchase such shares of common stock at a weighted-average price of \$1.50 per share.

Option grants and issuances of common stock upon exercise of such options were exempt pursuant to Rule 701 and Section 4(2) of the Securities Act. All recipients either received adequate information about us or had access, through employment or other relationships, to such information.

## **Item 16. Exhibits and financial statement schedules**

### **(a) Exhibits**

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

### **(b) Financial statement schedules**

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

## **Item 17. Undertakings**

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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The undersigned Registrant hereby undertakes:

- (1) That for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) That for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Cambridge, Commonwealth of Massachusetts, on March 3, 2014.

**AKEBIA THERAPEUTICS, INC.**

By: /s/ John P. Butler  
John P. Butler  
*Chief Executive Officer and President*

**Signatures**

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form S-1 has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ John P. Butler</u> John P. Butler	Chief Executive Officer and President (Principal Executive Officer)	March 3, 2014
<u>*</u> Jason A. Amello	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)	March 3, 2014
<u>*</u> Muneer A. Satter	Director	March 3, 2014
<u>*</u> Campbell Murray, M.D.	Director	March 3, 2014
<u>*</u> Jack Nielsen	Director	March 3, 2014
<u>*</u> Anupam Dalal, M.D.	Director	March 3, 2014
<u>*</u> Giovanni Ferrara	Director	March 3, 2014
<u>*</u> Kim Dueholm, Ph.D.	Director	March 3, 2014
<u>*</u> Duane Nash, M.D.	Director	March 3, 2014



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<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>*</u> Michael S. Wyzga	Director	March 3, 2014

\*By: /s/ John P. Butler  
John P. Butler  
Attorney-in-fact

## EXHIBIT INDEX

<u>Exhibit number</u>	<u>Description of Exhibit</u>
1.1	Form of Underwriting Agreement
3.1	Form of Amended and Restated Certificate of Incorporation (to be effective upon completion of this offering)
3.2	Form of Amended and Restated Bylaws (to be effective upon completion of this offering)
3.3**	Eighth Amended and Restated Certificate of Incorporation (currently in effect)
3.4**	Bylaws of the Registrant, as amended (currently in effect)
3.5*	Amendment to Eighth Amended and Restated Certificate of Incorporation
4.1	Form of Common Stock Certificate
4.2**	Third Amended and Restated Voting Agreement, dated May 10, 2013
4.3**	Amendment No. 1 to the Third Amended and Restated Voting Agreement, dated May 31, 2013
4.4**	Third Amended and Restated Investors' Rights Agreement, dated May 10, 2013
4.5**	Amendment No. 1 to the Third Amended and Restated Investors' Rights Agreement, dated May 31, 2013
4.6**	Second Amended and Restated Right of First Refusal and Co-Sale Agreement, dated April 6, 2011
4.7**	Amendment Number One to Second Amended and Restated Right of First Refusal and Co-Sale Agreement, dated July 9, 2012
4.8**	Amendment Number Two to the Second Amended and Restated Right of First Refusal and Co-Sale Agreement, dated May 10, 2013
4.9	Form of Fourth Amended and Restated Investors' Rights Agreement
5.1*	Opinion of Ropes & Gray LLP
10.1	Form of Director and Officer Indemnification Agreement
10.2**	Office Lease Agreement Between MA-Riverview/245 First Street, L.L.C. and Akebia Therapeutics, Inc., dated December 3, 2013
10.3**	Amended and Restated Administrative Services Agreement, between Akebia Therapeutics, Inc. and Aerpio Therapeutics, Inc., dated August 27, 2012
10.4**	Administrative Services Agreement, between Akebia Therapeutics, Inc. and Aerpio Therapeutics, Inc., dated November 1, 2012
10.5†**	Amended and Restated 2008 Equity Incentive Plan
10.6†**	Amendment No. 1 to Amended and Restated 2008 Equity Incentive Plan
10.7†**	Executive Employment Agreement with John P. Butler, dated September 16, 2013
10.8†**	Executive Employment Agreement with Jason A. Amello, dated September 23, 2013
10.9†**	Offer Letter to Nicole R. Hadas, dated November 13, 2013
10.10†**	Executive Employment Agreement with Dr. Robert Shalwitz, Dated April 6, 2011
10.11†**	Offer Letter to William Daly, Dated January 7, 2012
10.12†**	Consulting Agreement with William Daly, dated February 7, 2014
10.13†**	Separation Agreement with William Daly, dated February 7, 2014
10.14†**	Executive Employment Agreement with Joseph H. Gardner, dated May 2, 2007
10.15†**	Amendment No. 1 to Executive Employment Agreement, dated April 6, 2010
10.16†**	Consulting Agreement with Joseph H. Gardner, dated September 15, 2013
10.17†**	Separation Agreement with Joseph H. Gardner, dated September 15, 2013

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<u>Exhibit number</u>	<u>Description of Exhibit</u>
10.18†**	Amended and Restated Partial Recourse Promissory Note, dated May 9, 2013, with Joseph Gardner
10.19†**	Amended and Restated Partial Recourse Promissory Note, dated June 15, 2013, with Joseph Gardner
10.20†**	Amended and Restated Partial Recourse Promissory Note, dated May 9, 2013, with Robert Shalwitz
10.21†**	Amended and Restated Partial Recourse Promissory Note, dated June 15, 2013, with Robert Shalwitz
10.22†**	Forgiveness and Release Agreement, dated January 30, 2014, with Robert Shalwitz
10.23†	Form of Non-Statutory Stock Option Agreement for non-officer employees
10.24†	Form of Non-Statutory Stock Option Agreement for officers
10.25†	Form of Non-Statutory Stock Option Agreement for non-employee directors
10.26†	Non-Employee Director Compensation Program
10.27†	Form of Executive Severance Agreement for officers
10.28†	Form of Executive Severance Agreement for non-officer employees at the Vice President level or higher
10.29†	2014 Incentive Plan
10.30†	2014 Employee Stock Purchase Plan
10.31†	Cash Incentive Plan
10.32#	Master Services Agreement by and between Evonik Corporation and Akebia Therapeutics, Inc., dated February 28, 2014
23.1	Consent of Ernst & Young LLP
23.2*	Consent of Ropes & Gray LLP (included in Exhibit 5.1)
24.1**	Power of Attorney (included on signature page)

*	To be filed by amendment.
**	Previously filed.
†	Indicates a management contract or compensatory plan.
#	Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been submitted separately to the SEC.

Shares

AKEBIA THERAPEUTICS, INC.

COMMON STOCK, PAR VALUE \$0.00001 PER SHARE

UNDERWRITING AGREEMENT

, 2014

Morgan Stanley & Co. LLC  
Credit Suisse Securities (USA) LLC  
UBS Securities LLC

c/o Morgan Stanley & Co. LLC  
1585 Broadway  
New York, New York 10036

and

Credit Suisse Securities (USA) LLC  
Eleven Madison Avenue  
New York, New York 10010-3629

and

UBS Securities LLC  
299 Park Avenue  
New York, New York 10171

Ladies and Gentlemen:

Akebia Therapeutics, Inc., a Delaware corporation (the “**Company**”), proposes to issue and sell to the several Underwriters named in Schedule I hereto (the “**Underwriters**”), for whom you are acting as representatives (the “**Representatives**”) shares of its common stock, par value \$0.00001 per share (the “**Firm Shares**”). The Company also proposes to issue and sell to the several Underwriters not more than an additional shares of its common stock, par value \$0.00001 per share, (the “**Additional Shares**”) if and to the extent that you, as Representatives of the Underwriters, shall have determined to exercise, on behalf of the Underwriters, the right to purchase such shares of common stock granted to the Underwriters in Section 2 hereof. The Firm Shares and the Additional Shares are hereinafter collectively referred to as the “**Shares**.” The shares of common stock, par value \$ per share, of the Company to be outstanding after giving effect to the sales contemplated hereby are hereinafter referred to as the “**Common Stock**.”

The Company has filed with the Securities and Exchange Commission (the “**Commission**”) a registration statement, including a prospectus, relating to the Shares. The registration statement as amended at the time it becomes effective, including the information (if any) deemed to be part of the registration statement at the time of effectiveness pursuant to Rule 430A under the Securities Act of 1933, as amended (the “**Securities Act**”), is hereinafter referred to as the “**Registration Statement**”; the prospectus in the form first used to confirm sales of Shares (or in the form first made

available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act) is hereinafter referred to as the “**Prospectus.**” If the Company has filed an abbreviated registration statement to register additional shares of Common Stock pursuant to Rule 462(b) under the Securities Act (the “**Rule 462 Registration Statement**”), then any reference herein to the term “**Registration Statement**” shall be deemed to include such Rule 462 Registration Statement.

For purposes of this Agreement, “**free writing prospectus**” has the meaning set forth in Rule 405 under the Securities Act, “**Time of Sale Prospectus**” means the preliminary prospectus together with the documents and pricing information set forth in Schedule II hereto, and “**broadly available road show**” means a “bona fide electronic road show” as defined in Rule 433(h)(5) under the Securities Act that has been made available without restriction by means of graphic communication to any person. As used herein, the terms “Registration Statement,” “preliminary prospectus,” “Time of Sale Prospectus” and “Prospectus” shall include the documents, if any, incorporated by reference therein as of the date hereof.

Morgan Stanley & Co. LLC (“**Morgan Stanley**”) has agreed to reserve a portion of the Shares to be purchased by it under this Agreement for sale to the Company’s directors, officers, employees and business associates and other parties related to the Company (collectively, “**Participants**”), as set forth in the Prospectus under the heading “Underwriting” (the “**Directed Share Program**”). The Shares to be sold by Morgan Stanley and its affiliates pursuant to the Directed Share Program are referred to hereinafter as the “**Directed Shares**”. Any Directed Shares not orally confirmed for purchase by any Participant by 11:00 a.m., New York City time, on the business day following the day on which this Agreement is executed will be offered to the public by the Underwriters as set forth in the Prospectus.

1. *Representations and Warranties.* The Company represents and warrants to and agrees with each of the Underwriters that:

(a) The Registration Statement has become effective; no stop order suspending the effectiveness of the Registration Statement is in effect, and no proceedings for such purpose are pending before or threatened by the Commission.

(b) (i) The Registration Statement, when it became effective, did not contain and, as amended or supplemented, if applicable, will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) the Registration Statement and the Prospectus comply and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder, (iii) the Time of Sale Prospectus does not, and at the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers and at the Closing Date (as defined in Section 4), the Time of Sale Prospectus, as then amended or supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances

under which they were made, not misleading, (iv) each broadly available road show, if any, when considered together with the Time of Sale Prospectus, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading and (v) the Prospectus does not contain and, as amended or supplemented, if applicable, will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, except that the representations and warranties set forth in this paragraph do not apply to statements or omissions in the Registration Statement, the Time of Sale Prospectus or the Prospectus based upon information furnished in writing to the Company by any Underwriter through you expressly for use therein.

(c) The Company is not an “ineligible issuer” in connection with the offering pursuant to Rules 164, 405 and 433 under the Securities Act. Any free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Except for the free writing prospectuses, if any, identified in Schedule II hereto, and electronic road shows, if any, each furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior consent, prepare, use or refer to, any free writing prospectus.

(d) The Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own its property and to conduct its business as described in the Time of Sale Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not have a material adverse effect on the Company.

(e) The Company has no subsidiaries.

(f) This Agreement has been duly authorized, executed and delivered by the Company.

(g) The authorized capital stock of the Company conforms as to legal matters to the description thereof contained in each of the Time of Sale Prospectus and the Prospectus.

(h) The shares of Common Stock outstanding prior to the issuance of the Shares have been duly authorized and are validly issued, fully paid and non-assessable.

(i) The Shares have been duly authorized and, when issued and delivered in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable, and the issuance of such Shares will not be subject to any preemptive or similar rights that have not been waived.

(j) The execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement will not contravene any provision of applicable law or the certificate of incorporation or by-laws of the Company or any agreement or other instrument binding upon the Company that is material to the Company, or any judgment, order or decree of any governmental body, agency or court having jurisdiction over the Company, and no consent, approval, authorization or order of, or qualification with, any governmental body or agency is required for the performance by the Company of its obligations under this Agreement, except such as may be required by the securities or Blue Sky laws of the various states in connection with the offer and sale of the Shares.

(k) There has not occurred any material adverse change, or any development involving a prospective material adverse change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company from that set forth in the Time of Sale Prospectus.

(l) There are no legal or governmental proceedings pending or threatened to which the Company is a party or to which any of the properties of the Company is subject (i) other than proceedings accurately described in all material respects in the Time of Sale Prospectus and proceedings that would not reasonably be expected to have a material adverse effect on the Company or on the power or ability of the Company to perform its obligations under this Agreement or (ii) that are required to be described in the Registration Statement or the Prospectus and are not so described; and there are no statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement that are not described or filed as required.

(m) The Time of Sale Prospectus filed as part of the registration statement or as part of any amendment thereto, or filed pursuant to Rule 424 under the Securities Act, complied when so filed in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder.

(n) The Company is not, and after giving effect to the offering and sale of the Shares and the application of the proceeds thereof as described in the Prospectus will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.

(o) The Company (i) is in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) has received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their



respective businesses and (iii) is in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company.

(p) There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) which would, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company.

(q) There are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company or to require the Company to include such securities with the Shares registered pursuant to the Registration Statement that have not been waived.

(r) Neither the Company nor any of its affiliates, nor any director, officer, or employee, nor, to the Company's knowledge, any agent or representative of the Company or of any of its affiliates, has taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment or giving of money, property, gifts or anything else of value, directly or indirectly, to any "government official" (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office) to influence official action or secure an improper advantage; and the Company and affiliates have conducted their businesses in compliance with applicable anti-corruption laws and have instituted and maintain policies and procedures designed to promote and achieve compliance with such laws and with the representation and warranty contained herein.

(s) The operations of the Company are and have been conducted at all times in material compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Anti-Money Laundering Laws**"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Anti-Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(t) (i) Neither the Company nor any director, officer, or employee thereof, nor, to the Company's knowledge, any agent, affiliate or representative of the Company, is an individual or entity ("**Person**") that is, or is owned or controlled by a Person that is:

(A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("**OFAC**"), the United Nations Security Council ("**UNSC**"), the European Union ("**EU**"), Her Majesty's Treasury ("**HMT**"), or other relevant sanctions authority (collectively, "**Sanctions**"), nor

(B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Cuba, Iran, North Korea, Sudan and Syria).

(ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:

(A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) For the past 5 years, the Company has not knowingly engaged in and is not now knowingly engaged in any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(u) Subsequent to the respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus,

(i) the Company has not incurred any material liability or obligation, direct or contingent, nor entered into any material transaction; (ii) the Company has not purchased any of its outstanding capital stock, nor declared, paid or otherwise made any dividend or distribution of any kind on its capital stock other than ordinary and customary dividends; and (iii) there has not been any material change in the capital stock, short-term debt or long-term debt of the Company, except in each case as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, respectively.

(v) The Company does not own any real property. The Company has good and marketable title to all personal property owned by them which is material to the business of the Company, in each case free and clear of all liens, encumbrances and defects except such as are described in the Time of Sale Prospectus or such as do not materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company; and any real property and

buildings held under lease by the Company are held by it under valid, subsisting and enforceable leases with such exceptions as would not reasonably be expected to have a material adverse effect on the Company, except as described in the Time of Sale Prospectus.

(w) The Company owns or is licensed rights to, or otherwise has rights to exploit, all Intellectual Property (as defined below) necessary for the conduct of the Company's business as now currently conducted or as currently proposed to be conducted by it in the future as disclosed in the Time of Sale Prospectus, except as disclosed in the Time of Sale Prospectus or except as would not reasonably be expected to have a material adverse effect on the Company. There is no infringement, misappropriation or violation, or the occurrence of any event that with notice or the passage of time would constitute any of the foregoing, (i) by third parties of any Intellectual Property owned by or licensed to the Company or (ii) by the Company of any Intellectual Property of any third parties, in each case, except as disclosed in the Time of Sale Prospectus or except as would not reasonably be expected to have a material adverse effect on the Company. There is no pending, or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others to which the Company is a party or otherwise, challenging the Company's rights in or to, or exploitation of, any such Intellectual Property, except as disclosed in the Time of Sale Prospectus. Such Intellectual Property owned by the Company and, to the knowledge of the Company, such Intellectual Property licensed to the Company have not been adjudged invalid or unenforceable, in whole or in part, and there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any such Intellectual Property, except as disclosed in the Time of Sale Prospectus. There is no pending, or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, the Company has not received any written notice of such claim and the Company has no knowledge of any other fact which would form a reasonable basis for any such claim. The Company has complied with the terms of each agreement pursuant to which any Intellectual Property has been licensed to the Company, and all such agreements are in full force and effect, except as would not reasonably be expected to have a material adverse effect. None of the Intellectual Property used by the Company in its business has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company. No employee or independent contractor of the Company is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer or independent contractor where the basis of such violation relates to such employee's employment or independent contractor's engagement with the Company or actions undertaken while employed or engaged with the Company, except as disclosed in the Time of Sale Prospectus. "**Intellectual Property**" shall mean all patents, patent rights, trade and service marks, trade names, copyrights, licenses, inventions, trade secrets, domain names, and registrations and applications for registration thereof.

(x) No material labor dispute with the employees of the Company exists, except as described in the Time of Sale Prospectus, or, to the knowledge of the Company, is imminent; and the Company is not aware of any existing, threatened or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers or contractors that would reasonably be expected to have a material adverse effect on the Company.

(y) The Company is insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as management of the Company reasonably believes are prudent and customary in the businesses in which they are engaged; the Company has not been refused any insurance coverage sought or applied for; and the Company has no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage is scheduled to expire or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a material adverse effect on the Company, except as described in the Time of Sale Prospectus.

(z) The Company has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the U.S. Food and Drug Administration (“**FDA**”) or any similar regulatory authority alleging or asserting noncompliance by the Company. The Company is not a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, plan of correction or similar agreement imposed by any governmental authority.

(aa) The Company, and to the Company’s knowledge, its respective directors, officers, employees, agents, affiliates and representatives, are, and at all times have been, in compliance in all material respects with all health care laws applicable to the Company or any of its respective products or activities, including, but not limited to, the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the civil False Claims Act (31 U.S.C. §§3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the exclusion laws (42 U.S.C. § 1320a-7), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), the Public Health Service Act (42 U.S.C. § 201 et seq.), any similar local, state or federal laws, and the regulations promulgated pursuant to such laws (collectively, the “**Health Care Laws**”), and have not engaged in activities which are, as applicable, prohibited or cause for civil penalties or mandatory or permissive exclusion from Medicare, Medicaid, or any other state health care program or federal health care program. The Company has not received any notification, correspondence or any other written or oral communication, including, without limitation, notification of any pending or threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action, from any governmental authority of potential or actual non-compliance by, or liability of, the Company under any Health Care Laws.

(bb) The Company possesses, and is in compliance in all material respects with the terms of, all certificates, approvals, clearances, registrations, exemptions, franchises, licenses, permits and other authorizations necessary to conduct their respective businesses (collectively, “**Licenses**”), including, without limitation, all Licenses required by the FDA and/or by any other U.S., state, local or foreign government or drug regulatory agency (collectively, the “**Regulatory Agencies**”). All Licenses are in full force and effect and the Company is not in violation of any term of any License in any material respect. The Company has fulfilled and performed all of its obligations in all material respects with respect to the Licenses and, to the Company’s knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the holder of any License. The Company has not received any notice of proceedings relating to the revocation or modification of any Licenses that, if determined adversely to the Company, would reasonably be expected to have a material impact on the Company. To the Company’s knowledge, no Regulatory Agency has taken any action to limit, suspend or revoke any License possessed by the Company.

(cc) The preclinical tests and clinical trials that are described in, or the results of which are referred to in, the Time of Sale Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols established for each such preclinical test or clinical trial and all Health Care Laws, including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58 and 312, and, where applicable, the EU Clinical Trials Directive (Directive 2001/20/EC) as implemented; each description of such tests and trials, and the results thereof, contained in the Time of Sale Prospectus is accurate and complete in all material respects and fairly presents the data about and derived from such tests and trials, and the Company has no knowledge of any other studies or tests the results of which call into question, the results described or referred to in the Time of Sale Prospectus; and the Company has not received any notices or other correspondence from FDA or any similar regulatory authority requiring the termination, suspension or material modification of any preclinical tests or clinical trials that are, or whose results of which are, described or referred to in the Time of Sale Prospectus.

(dd) Neither the Company nor, to the Company’s knowledge, any of its respective directors, officers, employees and agents, is debarred, suspended or excluded, or has been convicted of any crime or engaged in any conduct that could result in a debarment, suspension or exclusion, from any federal or state government health care program under 21 U.S.C. § 335a or any other Health Care Law. No claims, actions, proceedings or investigations that would reasonably be expected to result in such a debarment, suspension or exclusion are pending or, to the Company’s knowledge, threatened against the Company, or the directors, officers, employees or agents of the Company.

(ee) The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management’s general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets

is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as described in the Time of Sale Prospectus, since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness in the Company's internal control over financial reporting (whether or not remediated) identified by the Company and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(ff) Except as described in the Time of Sale Prospectus, the Company has not sold, issued or distributed any shares of Common Stock during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulation D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(gg) The Registration Statement, the Prospectus, the Time of Sale Prospectus and any preliminary prospectus comply, and any amendments or supplements thereto will comply, in all material respects, with any applicable laws or regulations of foreign jurisdictions in which the Prospectus, the Time of Sale Prospectus or any preliminary prospectus, as amended or supplemented, if applicable, are distributed in connection with the Directed Share Program.

(hh) No consent, approval, authorization or order of, or qualification with, any governmental body or agency, other than those obtained, is required in connection with the offering of the Directed Shares in any jurisdiction where the Directed Shares are being offered.

(ii) The Company has not offered, or caused Morgan Stanley to offer, Shares to any person pursuant to the Directed Share Program with the specific intent to unlawfully influence (i) a customer or supplier of the Company to alter the customer's or supplier's level or type of business with the Company, or (ii) a trade journalist or publication to write or publish favorable information about the Company or its products.

(jj) The Company has filed all federal, state, local and foreign tax returns required to be filed through the date of this Agreement or have requested extensions thereof (except where the failure to file would not, individually or in the aggregate, reasonably be expected to have a material adverse effect) and have paid all taxes required to be paid thereon (except for cases in which the failure to pay would not have a material adverse effect, or, except as currently being contested in good faith and for which adequate reserves required by U.S. GAAP have been created in the financial statements of the Company), and no tax deficiency has been determined adversely to the Company which has, individually or in the aggregate, had (nor does the Company have any notice or knowledge of any tax deficiency which would reasonably be expected to be determined adversely to the Company and which would reasonably be expected to, individually or in the aggregate, have) a material adverse effect on the Company.

(kk) From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an “emerging growth company,” as defined in Section 2(a) of the Securities Act (an “**Emerging Growth Company**”). “**Testing-the-Waters Communication**” means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(ll) The Company (i) has not alone engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications of which the Representatives have been informed with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that each of the Representatives has been authorized to act on its behalf in undertaking previously agreed upon Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule III hereto. “**Written Testing-the-Waters Communication**” means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(mm) As of the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers, none of (i) the Time of Sale Prospectus, (ii) any free writing prospectus, when considered together with the Time of Sale Prospectus, and (iii) any individual Written Testing-the-Waters Communication, when considered together with the Time of Sale Prospectus, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

2. *Agreements to Sell and Purchase.* The Company hereby agrees to sell to the several Underwriters, and each Underwriter, upon the basis of the representations and warranties herein contained, but subject to the conditions hereinafter stated, agrees, severally and not jointly, to purchase from the Company the respective numbers of Firm Shares set forth in Schedule I hereto opposite its name at \$        a share (the “**Purchase Price**”).

On the basis of the representations and warranties contained in this Agreement, and subject to its terms and conditions, the Company agrees to sell to the Underwriters the Additional Shares, and the Underwriters shall have the right to purchase, severally and not jointly, up to        Additional Shares at the Purchase Price, provided, however, that the amount paid by the Underwriters for any Additional Shares shall be reduced by an amount per share equal to any dividends declared by the Company and payable on the Firm Shares but not payable on such Additional Shares. You may exercise this right on behalf of the Underwriters in whole or from time to time in part by giving written notice not later than 30 days after the date of this Agreement. Any

exercise notice shall specify the number of Additional Shares to be purchased by the Underwriters and the date on which such shares are to be purchased. Each purchase date must be at least one business day after the written notice is given and may not be earlier than the closing date for the Firm Shares nor later than ten business days after the date of such notice. Additional Shares may be purchased as provided in Section 4 hereof solely for the purpose of covering over-allotments made in connection with the offering of the Firm Shares. On each day, if any, that Additional Shares are to be purchased (an “**Option Closing Date**”), each Underwriter agrees, severally and not jointly, to purchase the number of Additional Shares (subject to such adjustments to eliminate fractional shares as you may determine) that bears the same proportion to the total number of Additional Shares to be purchased on such Option Closing Date as the number of Firm Shares set forth in Schedule I hereto opposite the name of such Underwriter bears to the total number of Firm Shares.

3. *Terms of Public Offering.* The Company is advised by you that the Underwriters propose to make a public offering of their respective portions of the Shares as soon after the Registration Statement and this Agreement have become effective as in your judgment is advisable. The Company is further advised by you that the Shares are to be offered to the public initially at \$ \_\_\_\_\_ a share (the “**Public Offering Price**”) and to certain dealers selected by you at a price that represents a concession not in excess of \$ \_\_\_\_\_ a share under the Public Offering Price, and that any Underwriter may allow, and such dealers may reallow, a concession, not in excess of \$ \_\_\_\_\_ a share, to any Underwriter or to certain other dealers.

4. *Payment and Delivery.* Payment for the Firm Shares shall be made to the Company in Federal or other funds immediately available in New York City against delivery of such Firm Shares for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on \_\_\_\_\_, 2014, or at such other time on the same or such other date, not later than \_\_\_\_\_, 2014, as shall be mutually agreed in writing by you and the Company. The time and date of such payment are hereinafter referred to as the “**Closing Date**.”

Payment for any Additional Shares shall be made to the Company in Federal or other funds immediately available in New York City against delivery of such Additional Shares for the respective accounts of the several Underwriters at 10:00 a.m., New York City time, on the date specified in the corresponding notice described in Section 2 or at such other time on the same or on such other date, in any event not later than \_\_\_\_\_, 2014, as shall be mutually agreed in writing by you and the Company.

The Firm Shares and Additional Shares shall be registered in such names and in such denominations as you shall request in writing not later than one full business day prior to the Closing Date or the applicable Option Closing Date, as the case may be. The Firm Shares and Additional Shares shall be delivered to you on the Closing Date or an Option Closing Date, as the case may be, for the respective accounts of the several Underwriters, with any transfer taxes payable in connection with the transfer of the Shares to the Underwriters duly paid, against payment of the Purchase Price therefor.



5. *Conditions to the Underwriters' Obligations.* The obligations of the Company to sell the Shares to the Underwriters and the several obligations of the Underwriters to purchase and pay for the Shares on the Closing Date are subject to the condition that the Registration Statement shall have become effective not later than p.m. (New York City time) on the date hereof.

The several obligations of the Underwriters are subject to the following further conditions:

(a) Subsequent to the execution and delivery of this Agreement and prior to the Closing Date:

(i) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any of the securities of the Company by any "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"); and

(ii) there shall not have occurred any change, or any development involving a prospective change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company, from that set forth in the Time of Sale Prospectus that, in your judgment, is material and adverse and that makes it, in your judgment, impracticable to market the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus.

(b) The Underwriters shall have received on the Closing Date a certificate, dated the Closing Date and signed by an executive officer of the Company, to the effect set forth in Section 5(a)(i) above and to the effect that the representations and warranties of the Company contained in this Agreement are true and correct as of the Closing Date and that the Company has complied in all material respects with all of the agreements and satisfied all of the conditions on its part to be performed or satisfied hereunder on or before the Closing Date.

The officer signing and delivering such certificate may rely upon the best of his or her knowledge as to proceedings threatened.

(c) The Underwriters shall have received on the Closing Date an opinion of Ropes & Gray LLP, outside counsel for the Company, dated the Closing Date, in form and substance satisfactory to the Representatives.

(d) The Underwriters shall have received on the Closing Date an opinion of Jones Day LLP, intellectual property counsel for the Company, dated the Closing Date, in form and substance satisfactory to the Representatives.

(e) The Underwriters shall have received on the Closing Date an opinion of Latham & Watkins LLP, counsel for the Underwriters, dated the Closing Date, in form and substance satisfactory to the Representatives.

The opinion of Ropes & Gray LLP described in Section 5(c) above and the opinion of Jones Day LLP described in Section 5(d) above shall be rendered to the Underwriters at the request of the Company and shall so state therein.

(f) The Underwriters shall have received, on each of the date hereof and the Closing Date, a letter dated the date hereof or the Closing Date, as the case may be, in form and substance satisfactory to the Underwriters, from Ernst & Young LLP, independent public accountants, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus; *provided* that the letter delivered on the Closing Date shall use a "cut-off date" not earlier than the date hereof.

(g) The "lock-up" agreements, each substantially in the form of Exhibit A hereto, between you and all of the shareholders, option holders, officers and directors of the Company relating to sales and certain other dispositions of shares of Common Stock or certain other securities listed on Schedule IV, delivered to you on or before the date hereof, shall be in full force and effect on the Closing Date.

(h) The several obligations of the Underwriters to purchase Additional Shares hereunder are subject to the delivery to you on the applicable Option Closing Date of the following:

(i) a certificate, dated the Option Closing Date and signed by an executive officer of the Company, confirming that the certificate delivered on the Closing Date pursuant to Section 5(b) hereof remains true and correct as of such Option Closing Date;

(ii) an opinion of Ropes & Gray LLP, outside counsel for the Company, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(c) hereof;

(iii) an opinion of Jones Day LLP, intellectual property counsel for the Company, dated the Option Closing Date, to the same effect as the opinion required by Section 5(d) hereof;

(iv) an opinion of Latham & Watkins LLP, counsel for the Underwriters, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(e) hereof;

(v) a letter dated the Option Closing Date, in form and substance satisfactory to the Underwriters, from Ernst & Young LLP,

independent public accountants, substantially in the same form and substance as the letter furnished to the Underwriters pursuant to Section 5(f) hereof; *provided* that the letter delivered on the Option Closing Date shall use a “cut-off date” not earlier than three business days prior to such Option Closing Date; and

(vi) such other documents as you may reasonably request with respect to the good standing of the Company, the due authorization and issuance of the Additional Shares to be sold on such Option Closing Date and other matters related to the issuance of such Additional Shares.

6. *Covenants of the Company.* The Company covenants with each Underwriter as follows:

(a) To furnish to you, without charge, five signed copies of the Registration Statement (including exhibits thereto) and for delivery to each other Underwriter a conformed copy of the Registration Statement (without exhibits thereto) and to furnish to you in New York City, without charge, prior to 10:00 a.m., New York City time, on the business day next succeeding the date of this Agreement and during the period mentioned in Section 6(e) or 6(f) below, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) Before amending or supplementing the Registration Statement, the Time of Sale Prospectus or the Prospectus, to furnish to you a copy of each such proposed amendment or supplement and not to file any such proposed amendment or supplement to which you reasonably object, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) To furnish to you a copy of each proposed free writing prospectus to be prepared by or on behalf of, used by, or referred to by the Company and not to use or refer to any proposed free writing prospectus to which you reasonably object.

(d) Not to take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Underwriter that the Underwriter otherwise would not have been required to file thereunder.

(e) If the Time of Sale Prospectus is being used to solicit offers to buy the Shares at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus in order to make the statements therein, in the light of the circumstances, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement then on file, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to

comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not, in the light of the circumstances when the Time of Sale Prospectus is delivered to a prospective purchaser, be misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) If, during such period after the first date of the public offering of the Shares as in the opinion of counsel for the Underwriters the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is required by law to be delivered in connection with sales by an Underwriter or dealer, any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, not misleading, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to the dealers (whose names and addresses you will furnish to the Company) to which Shares may have been sold by you on behalf of the Underwriters and to any other dealers upon request, either amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, be misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law.

(g) To endeavor to qualify the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions as you shall reasonably request.

(h) To make generally available to the Company's security holders and to you as soon as practicable an earning statement covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(i) To comply with all applicable securities and other laws, rules and regulations in each jurisdiction in which the Directed Shares are offered in connection with the Directed Share Program.

(j) Whether or not the transactions contemplated in this Agreement are consummated or this Agreement is terminated, to pay or cause to be paid all expenses incident to the performance of the Company's obligations under this Agreement, including: (i) the fees, disbursements and expenses of the Company's counsel and the Company's accountants in connection with the registration and delivery of the Shares under the Securities Act and all other fees or expenses incurred by the Company in

connection with the preparation and filing of the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company and amendments and supplements to any of the foregoing, including all printing costs associated therewith, and the mailing and delivering of copies thereof to the Underwriters and dealers, in the quantities hereinabove specified, (ii) all costs and expenses related to the transfer and delivery of the Shares to the Underwriters, including any transfer or other taxes payable thereon, (iii) the cost of printing or producing any Blue Sky or Legal Investment memorandum in connection with the offer and sale of the Shares under state securities laws and all expenses in connection with the qualification of the Shares for offer and sale under state securities laws as provided in Section 6(g) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the Blue Sky or Legal Investment memorandum, (iv) all filing fees and the reasonable fees and disbursements of counsel to the Underwriters incurred in connection with the review and qualification of the offering of the Shares by the Financial Industry Regulatory Authority, (v) all fees and expenses incurred by the Company in connection with the preparation and filing of the registration statement on Form 8-A relating to the Common Stock and all costs and expenses incident to listing the Shares on the NASDAQ Global Market, (vi) the cost of printing certificates representing the Shares, (vii) the costs and charges of any transfer agent, registrar or depository, (viii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives and officers of the Company and any such consultants, and fifty percent (50%) of the cost of any aircraft chartered in connection with the road show, (ix) the document production charges and expenses associated with printing this Agreement, (x) all fees and disbursements of counsel reasonably incurred by the Underwriters in connection with the Directed Share Program, and stamp duties, similar taxes or duties or other taxes, if any, incurred by the Underwriters in connection with the Directed Share Program and (xi) all other costs and expenses incident to the performance of the obligations of the Company hereunder for which provision is not otherwise made in this Section; provided that the amount payable by the Company pursuant to the foregoing clauses (iii) and (iv) shall not exceed in the aggregate \$50,000. It is understood, however, that except as provided in this Section, Section 8 entitled "Indemnity and Contribution", Section 9 entitled "Directed Share Program Indemnification" and the last paragraph of Section 11 below, the Underwriters will pay all of their costs and expenses, including fees and disbursements of their counsel, stock transfer taxes payable on resale of any of the Shares by them and any advertising expenses connected with any offers they may make.

(k) The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Shares within the meaning of the Securities Act and (ii) completion of the Restricted Period (as defined in this Section 6).

(l) If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

The Company also covenants with each Underwriter that, without the prior written consent of Morgan Stanley and Credit Suisse Securities (USA) LLC on behalf of the Underwriters, it will not, during the period ending 180 days after the date of the Prospectus (the "**Restricted Period**"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise or (3) file any registration statement with the Commission relating to the offering of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock.

The restrictions contained in the preceding paragraph shall not apply to (a) the Shares to be sold hereunder, (b) the issuance by the Company of shares of Common Stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof of which the Underwriters have been advised in writing, the grant of new options or other equity awards under employee or non-employee director benefit plans existing as the date hereof and disclosed in the Time of Sale Prospectus, and the filing of one or more registration statements on Form S-8 relating thereto, (c) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, *provided* that (i) such plan does not provide for the transfer of Common Stock during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Common Stock may be made under such plan during the Restricted Period, or (d) the offer or issuance of up to an aggregate of 5% of shares of Common Stock outstanding in connection with collaboration, intellectual property license or acquisition agreements or arrangements; *provided further*, that in the cases of clauses (b) and (d), that the recipients of such shares agree to be bound by a "lock-up" agreement in the form of Exhibit A hereto and delivers such agreement to Morgan Stanley and Credit Suisse Securities (USA) LLC prior to such issuance.

If Morgan Stanley and Credit Suisse Securities (USA) LLC, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up letter described

in Section 5(g) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two business days before the effective date of the release or waiver.

7. *Covenants of the Underwriters.* Each Underwriter severally covenants with the Company not to take any action that would result in the Company being required to file with the Commission under Rule 433(d) a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not be required to be filed by the Company thereunder, but for the action of the Underwriter.

8. *Indemnity and Contribution.* (a) The Company agrees to indemnify and hold harmless each Underwriter, each person, if any, who controls any Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act and each affiliate of any Underwriter within the meaning of Rule 405 under the Securities Act from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other expenses reasonably incurred in connection with defending or investigating any such action or claim) caused by any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any amendment thereof, any preliminary prospectus, the Time of Sale Prospectus or any amendment or supplement thereto, any issuer free writing prospectus as defined in Rule 433(h) under the Securities Act, any Company information that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act, any road show as defined in Rule 433(h) under the Securities Act (a "road show"), or the Prospectus or any amendment or supplement thereto, or any Written Testing-the-Waters Communication caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as such losses, claims, damages or liabilities are caused by any such untrue statement or omission or alleged untrue statement or omission based upon information furnished in writing to the Company by any Underwriter through you expressly for use therein.

(b) Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, its directors, its officers who sign the Registration Statement and each person, if any, who controls the Company within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the foregoing indemnity from the Company to such Underwriter, but only with reference to information furnished in writing to the Company by any Underwriter through you expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any issuer free writing prospectus, road show or the Prospectus or any amendment or supplement thereto.

(c) In case any proceeding (including any governmental investigation) shall be instituted involving any person in respect of which indemnity may be sought pursuant to Section 8(a) or 8(b), such person (the "**indemnified party**") shall promptly notify the

person against whom such indemnity may be sought (the “indemnifying party”) in writing and the indemnifying party, upon request of the indemnified party, shall retain counsel reasonably satisfactory to the indemnified party to represent the indemnified party and any others the indemnifying party may designate in such proceeding and shall pay the fees and disbursements of such counsel related to such proceeding. In any such proceeding, any indemnified party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. It is understood that the indemnifying party shall not, in respect of the legal expenses of any indemnified party in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all such indemnified parties and that all such fees and expenses shall be reimbursed as they are incurred. Such firm shall be designated in writing by Morgan Stanley, in the case of parties indemnified pursuant to Section 8(a), and by the Company, in the case of parties indemnified pursuant to Section 8(b). The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by the second and third sentences of this paragraph, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 90 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into, and (iii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding.

(d) To the extent the indemnification provided for in Section 8(a) or 8(b) is unavailable to an indemnified party or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then each indemnifying party under such paragraph, in lieu of indemnifying such indemnified party thereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other hand from the offering of the Shares or (ii) if the allocation provided by clause 8(d)(i) above is not permitted by applicable law, in such proportion as is appropriate to reflect



not only the relative benefits referred to in clause 8(d)(i) above but also the relative fault of the Company on the one hand and of the Underwriters on the other hand in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other hand in connection with the offering of the Shares shall be deemed to be in the same respective proportions as the net proceeds from the offering of the Shares (before deducting expenses) received by the Company and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover of the Prospectus, bear to the aggregate Public Offering Price of the Shares. The relative fault of the Company on the one hand and the Underwriters on the other hand shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Underwriters' respective obligations to contribute pursuant to this Section 8 are several in proportion to the respective number of Shares they have purchased hereunder, and not joint.

(e) The Company and the Underwriters agree that it would not be just or equitable if contribution pursuant to this Section 8 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in Section 8(d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages and liabilities referred to in Section 8(d) shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 8, no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the Shares underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The remedies provided for in this Section 8 are not exclusive and shall not limit any rights or remedies which may otherwise be available to any indemnified party at law or in equity.

(f) The indemnity and contribution provisions contained in this Section 8 and the representations, warranties and other statements of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any Underwriter, any person controlling any Underwriter or any affiliate of any Underwriter or by or on behalf of the Company, its officers or directors or any person controlling the Company and (iii) acceptance of and payment for any of the Shares.

9. *Directed Share Program Indemnification.* (a) The Company agrees to indemnify and hold harmless Morgan Stanley, each person, if any, who controls Morgan Stanley within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act and each affiliate of Morgan Stanley within the meaning of Rule 405 of the Securities Act ("**Morgan Stanley Entities**") from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other expenses reasonably incurred in connection with defending or investigating any such action or claim) (i) caused by any untrue statement or alleged untrue statement of a material fact contained in any material prepared by or with the consent of the Company for distribution to Participants in connection with the Directed Share Program or caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; (ii) caused by the failure of any Participant to pay for and accept delivery of Directed Shares that the Participant agreed to purchase; or (iii) related to, arising out of, or in connection with the Directed Share Program, other than losses, claims, damages or liabilities (or expenses relating thereto) that are finally judicially determined to have resulted from the bad faith or gross negligence of Morgan Stanley Entities.

(b) In case any proceeding (including any governmental investigation) shall be instituted involving any Morgan Stanley Entity in respect of which indemnity may be sought pursuant to Section 9(a), the Morgan Stanley Entity seeking indemnity, shall promptly notify the Company in writing and the Company, upon request of the Morgan Stanley Entity, shall retain counsel reasonably satisfactory to the Morgan Stanley Entity to represent the Morgan Stanley Entity and any others the Company may designate in such proceeding and shall pay the fees and disbursements of such counsel related to such proceeding. In any such proceeding, any Morgan Stanley Entity shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such Morgan Stanley Entity unless (i) the Company shall have agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the Company and the Morgan Stanley Entity and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. The Company shall not, in respect of the legal expenses of the Morgan Stanley Entities in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all Morgan Stanley Entities. Any such separate firm for the Morgan Stanley Entities shall be designated in writing by Morgan Stanley. The Company shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the Company agrees to indemnify the Morgan Stanley Entities from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time a Morgan Stanley Entity shall have requested the Company to reimburse it for fees and expenses of counsel as contemplated by the second and third sentences of this paragraph, the Company agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 90 days after receipt by the Company of the aforesaid request, (ii) the Company shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into, and (iii) the Company shall not have

reimbursed the Morgan Stanley Entity in accordance with such request prior to the date of such settlement. The Company shall not, without the prior written consent of Morgan Stanley, effect any settlement of any pending or threatened proceeding in respect of which any Morgan Stanley Entity is or could have been a party and indemnity could have been sought hereunder by such Morgan Stanley Entity, unless such settlement includes an unconditional release of the Morgan Stanley Entities from all liability on claims that are the subject matter of such proceeding.

(c) To the extent the indemnification provided for in Section 9(a) is unavailable to a Morgan Stanley Entity or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then the Company in lieu of indemnifying the Morgan Stanley Entity thereunder, shall contribute to the amount paid or payable by the Morgan Stanley Entity as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Morgan Stanley Entities on the other hand from the offering of the Directed Shares or (ii) if the allocation provided by clause 9(c)(i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause 9(c)(i) above but also the relative fault of the Company on the one hand and of the Morgan Stanley Entities on the other hand in connection with any statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Morgan Stanley Entities on the other hand in connection with the offering of the Directed Shares shall be deemed to be in the same respective proportions as the net proceeds from the offering of the Directed Shares (before deducting expenses) and the total underwriting discounts and commissions received by the Morgan Stanley Entities for the Directed Shares, bear to the aggregate Public Offering Price of the Directed Shares. If the loss, claim, damage or liability is caused by an untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact, the relative fault of the Company on the one hand and the Morgan Stanley Entities on the other hand shall be determined by reference to, among other things, whether the untrue or alleged untrue statement or the omission or alleged omission relates to information supplied by the Company or by the Morgan Stanley Entities and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

(d) The Company and the Morgan Stanley Entities agree that it would not be just or equitable if contribution pursuant to this Section 9 were determined by pro rata allocation (even if the Morgan Stanley Entities were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in Section 9(c). The amount paid or payable by the Morgan Stanley Entities as a result of the losses, claims, damages and liabilities referred to in the immediately preceding paragraph shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by the Morgan Stanley Entities in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 9, no Morgan Stanley Entity shall be required to contribute any amount in excess of the amount by which the total price at which the Directed Shares distributed to the public were offered to the public exceeds the

amount of any damages that such Morgan Stanley Entity has otherwise been required to pay. The remedies provided for in this Section 9 are not exclusive and shall not limit any rights or remedies which may otherwise be available to any indemnified party at law or in equity.

(e) The indemnity and contribution provisions contained in this Section 9 shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any Morgan Stanley Entity or the Company, its officers or directors or any person controlling the Company and (iii) acceptance of and payment for any of the Directed Shares.

10. *Termination.* The Underwriters may terminate this Agreement by notice given by you to the Company, if after the execution and delivery of this Agreement and prior to the Closing Date (i) trading generally shall have been suspended or materially limited on, or by, as the case may be, any of the New York Stock Exchange, the NYSE MKT, the NASDAQ Global Market, the Chicago Board of Options Exchange, the Chicago Mercantile Exchange or the Chicago Board of Trade, (ii) trading of any securities of the Company shall have been suspended on any exchange or in any over-the-counter market, (iii) a material disruption in securities settlement, payment or clearance services in the United States shall have occurred, (iv) any moratorium on commercial banking activities shall have been declared by Federal or New York State authorities or (v) there shall have occurred any outbreak or escalation of hostilities, or any change in financial markets or any calamity or crisis that, in your judgment, is material and adverse and which, singly or together with any other event specified in this clause (v), makes it, in your judgment, impracticable or inadvisable to proceed with the offer, sale or delivery of the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus or the Prospectus.

11. *Effectiveness; Defaulting Underwriters.* This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

If, on the Closing Date or an Option Closing Date, as the case may be, any one or more of the Underwriters shall fail or refuse to purchase Shares that it has or they have agreed to purchase hereunder on such date, and the aggregate number of Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is not more than one-tenth of the aggregate number of the Shares to be purchased on such date, the other Underwriters shall be obligated severally in the proportions that the number of Firm Shares set forth opposite their respective names in Schedule I bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as you may specify, to purchase the Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date; provided that in no event shall the number of Shares that any Underwriter has agreed to purchase pursuant to this Agreement be increased pursuant to this Section 11 by an amount in excess of one-ninth of such number of Shares without the written consent of such Underwriter. If, on the Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Firm Shares and the aggregate number of Firm Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Firm Shares to be purchased on such date, and arrangements satisfactory to you and the Company for the purchase of such Firm Shares are not made within 36 hours after such default, this Agreement shall terminate without liability on the part of any non-defaulting Underwriter or the Company. In any such case either you or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement, in the Time of Sale Prospectus, in the Prospectus or in any other documents or arrangements may be effected. If, on an Option Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Additional Shares and the aggregate number of Additional Shares with respect to which such default occurs is more than

one-tenth of the aggregate number of Additional Shares to be purchased on such Option Closing Date, the non-defaulting Underwriters shall have the option to (i) terminate their obligation hereunder to purchase the Additional Shares to be sold on such Option Closing Date or (ii) purchase not less than the number of Additional Shares that such non-defaulting Underwriters would have been obligated to purchase in the absence of such default. Any action taken under this paragraph shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

If this Agreement shall be terminated by the Underwriters, or any of them, because of any failure or refusal on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement, or if for any reason the Company shall be unable to perform its obligations under this Agreement (which, for the purposes of this Section 11, shall not include termination by the Underwriters pursuant to clauses (i), (iii), (iv) or (v) of Section 10), the Company will reimburse the Underwriters or such Underwriters as have so terminated this Agreement with respect to themselves, severally, for all out-of-pocket expenses (including the fees and disbursements of their counsel) reasonably incurred by such Underwriters in connection with this Agreement or the offering contemplated hereunder.

12. *Entire Agreement.* (a) This Agreement, together with any contemporaneous written agreements and any prior written agreements (to the extent not superseded by this Agreement) that relate to the offering of the Shares, represents the entire agreement between the Company and the Underwriters with respect to the preparation of any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, the conduct of the offering, and the purchase and sale of the Shares.

(b) The Company acknowledges that in connection with the offering of the Shares: (i) the Underwriters have acted at arms length, are not agents of, and owe no fiduciary duties to, the Company or any other person, (ii) the Underwriters owe the Company only those duties and obligations set forth in this Agreement and prior written agreements (to the extent not superseded by this Agreement), if any, and (iii) the Underwriters may have interests that differ from those of the Company. The Company waives to the full extent permitted by applicable law any claims it may have against the Underwriters arising from an alleged breach of fiduciary duty in connection with the offering of the Shares.

13. *Counterparts.* This Agreement may be signed in two or more counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

14. *Applicable Law.* This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York.

15. *Headings.* The headings of the sections of this Agreement have been inserted for convenience of reference only and shall not be deemed a part of this Agreement.

16. *Notices.* All communications hereunder shall be in writing and effective only upon receipt and (a) if to the Underwriters shall be delivered, mailed or sent to you (i) in care of Morgan Stanley & Co. LLC, 1585 Broadway, New York, New York 10036, Attention: Equity Syndicate Desk, with a copy to the Legal Department, (ii) in care of Credit Suisse Securities (USA) LLC, Eleven Madison Avenue, New York, New York, 10010-3629, Attention: LCD-IBD, and (iii) in care of UBS Securities LLC, 1285 Avenue of the Americas, New York, New York, 10019, Attention Syndicate; and (b) if to the Company shall be delivered, mailed or sent to 245 First Street, Suite 1100, Cambridge, Massachusetts 02142.

Very truly yours,

AKEBIA THERAPEUTICS, INC.

By: \_\_\_\_\_  
Name:  
Title:

Accepted of the date hereof

Morgan Stanley & Co. LLC  
Credit Suisse Securities (USA) LLC  
UBS Securities LLC

Acting severally on behalf of themselves and the several  
Underwriters named in Schedule I hereto

By: Morgan Stanley & Co. LLC

By: \_\_\_\_\_  
Name:  
Title:

By: Credit Suisse Securities (USA) LLC

By: \_\_\_\_\_  
Name:  
Title:

By: UBS Securities LLC

By: \_\_\_\_\_  
Name:  
Title:

By: \_\_\_\_\_  
Name:  
Title:

<u>Underwriter</u>	<u>Number of Firm Shares To Be Purchased</u>
Morgan Stanley & Co. LLC	
Credit Suisse Securities (USA) LLC	
UBS Securities LLC	
Nomura Securities International, Inc.	
Total:	



**Time of Sale Prospectus**

1. Preliminary Prospectus issued [date]
2. [identify all free writing prospectuses filed by the Company under Rule 433(d) of the Securities Act]
3. [free writing prospectus containing a description of terms that does not reflect final terms, if the Time of Sale Prospectus does not include a final term sheet]
4. [orally communicated pricing information such as price per share and size of offering if a Rule 134 pricing term sheet is used at the time of sale instead of a pricing term sheet filed by the Company under Rule 433(d) as a free writing prospectus]

**Written Testing-the-Waters Communications**

1. [To be listed]

**Persons Delivering Lock-up Agreements**

1. [To be listed]

IV-1

## [FORM OF LOCK-UP LETTER]

, 2014

Morgan Stanley & Co. LLC  
Credit Suisse Securities (USA) LLC  
UBS Securities LLC

c/o Morgan Stanley & Co. LLC  
1585 Broadway  
New York, NY 10036

and

Credit Suisse Securities (USA) LLC  
Eleven Madison Avenue  
New York, New York, 10010-3629

Ladies and Gentlemen:

The undersigned understands that Morgan Stanley & Co. LLC ("**Morgan Stanley**"), Credit Suisse Securities (USA) LLC ("**Credit Suisse**") and UBS Securities LLC ("**UBS**," and together with Morgan Stanley and Credit Suisse, the "**Representatives**") propose to enter into an Underwriting Agreement (the "**Underwriting Agreement**") with Akebia Therapeutics, Inc., a Delaware corporation (together with any successor, the "**Company**"), providing for the public offering (the "**Public Offering**") by the several Underwriters, including the Representatives (the "**Underwriters**"), of shares (the "**Shares**") of the Common Stock, par value \$0.00001 per share, of the Company (the "**Common Stock**").

To induce the Underwriters that may participate in the Public Offering to continue their efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of Morgan Stanley and Credit Suisse on behalf of the Underwriters, it will not, during the period commencing on the date of the first filing with the Securities and Exchange Commission of the Company's registration statement relating to the Public Offering and ending 180 days after the date of the final prospectus (the "**Restricted Period**") relating to the Public Offering (the "**Prospectus**"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock beneficially owned (as such term is used in Rule 13d-3 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")), by the undersigned or any other securities so owned

convertible into or exercisable or exchangeable for Common Stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise. The foregoing sentence shall not apply to (a) transactions relating to shares of Common Stock or other securities acquired in the Public Offering (other than any Company-directed shares of Common Stock purchased in the Public Offering by an officer or director of the Company) or in open market transactions after the date of the Underwriting Agreement; (b) transfers of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock as a bona fide gift; (c) transfers of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock by will or intestacy; (d) the exercise of options to purchase shares of Common Stock granted under a stock incentive plan or stock purchase plan of the Company existing as of the date hereof and described in the Prospectus, *provided* that any shares of Common Stock issued pursuant to such exercise shall be subject to the restrictions set forth herein; (e) transfers to the Company for the purpose of satisfying tax withholding obligations upon the vesting of other equity incentive awards granted under a stock incentive plan or stock purchase plan of the Company existing as of the date hereof and described in the Prospectus; (f) transfers or distributions not involving a disposition for value of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock to limited or general partners, stockholders or members of the undersigned, or if the undersigned is a corporation, to a wholly-owned subsidiary of the undersigned; (g) transfers of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock made by the undersigned to (1) any trust, corporation, partnership, limited liability company or other legal entity who, directly or indirectly, controls, is controlled by, or is under common control with the undersigned, (2) any trust or other legal entity for which the undersigned or the undersigned's spouse serves as trustee or investment advisor, or (3) any member of the immediate family of the undersigned or any trust or other legal entity for the direct or indirect benefit of the undersigned or any member of the immediate family of the undersigned; (h) transfers of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock pursuant to a sale of, or an offer to purchase, 100% of the outstanding shares of Common Stock, whether pursuant to a merger, tender offer or otherwise, to a third party or group of third parties, *provided* that in the event that such merger, tender offer or other transaction is not completed, the Common Stock and any security convertible into or exercisable or exchangeable for Common Stock shall remain subject to the restrictions set forth herein; (i) the conversion of the outstanding preferred stock of the Company into shares of Common Stock upon the closing of the Public Offering, *provided* that such shares of Common Stock shall remain subject to the restrictions set forth herein; or (j) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, *provided* that (1) such plan does not provide for the transfer of Common Stock during the Restricted Period and (2) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the

effect that no transfer of Common Stock may be made under such plan during the Restricted Period; *provided, however*, that in the case of (1) any transfer or distribution pursuant to clause (b), (c), (f) or (g), each donee, distributee or transferee shall sign and deliver a lock-up letter substantially in the form of this letter and (2) any transaction, transfer, exercise or distribution pursuant to clause (a), (b), (c), (d), (e), (f), or (g), no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of Common Stock, shall be required or shall be voluntarily made during the Restricted Period (other than a filing on Form 5 made after the expiration of the Restricted Period). In addition, the undersigned agrees that, without the prior written consent of Morgan Stanley and Credit Suisse on behalf of the Underwriters, it will not, during the Restricted Period, make any demand for or exercise any right with respect to, the registration of any shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock; *provided that* the undersigned may make a demand under any registration rights agreement with the Company existing as of the date hereof and described in the Prospectus for, and exercise its rights under any such registration rights agreement with respect to, the registration after the expiration of the Restricted Period of shares of Common Stock that does not require the filing of a registration statement or any public announcement or activity regarding the registration during Restricted Period (and no such public announcement or activity shall be voluntarily made or taken during the Restricted Period). The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's shares of Common Stock except in compliance with the foregoing restrictions.

If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any issuer-directed Shares the undersigned may purchase in the offering.

If the undersigned is an officer or director of the Company, (i) Morgan Stanley and Credit Suisse agree that, at least three business days before the effective date of any release or waiver of the foregoing restrictions in connection with a transfer of shares of Common Stock, Morgan Stanley and Credit Suisse notify the Company of the impending release or waiver, and (ii) the Company has agreed in the Underwriting Agreement to announce the impending release or waiver by press release through a major news service at least two business days before the effective date of the release or waiver. Any release or waiver granted by Morgan Stanley and Credit Suisse hereunder to any such officer or director shall only be effective two business days after the publication date of such press release. The provisions of this paragraph will not apply if (a) the release or waiver is effected solely to permit a transfer not for consideration and (b) the transferee has agreed in writing to be bound by the same terms described in this letter to the extent and for the duration that such terms remain in effect at the time of the transfer.

In the event that during the Restricted Period, Morgan Stanley and Credit Suisse waive any prohibition on the transfer of shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock held by any person or entity that beneficially owns 5% or more of the outstanding shares of Common Stock, Morgan Stanley and Credit Suisse shall be deemed to have also waived, on the same

terms, the prohibitions set forth in this lock-up letter that would otherwise have applied to the undersigned with respect to the same percentage of the undersigned's Common Stock or securities convertible into or exercisable or exchangeable for Common Stock as the relative percentage of aggregate Common Stock or securities convertible into or exercisable or exchangeable for Common Stock held by such party receiving the waiver which are subject to such waiver. The provisions of this paragraph will not apply: (1) unless and until Morgan Stanley and Credit Suisse have first waived more than 1.0% of the Company's total outstanding shares of Common Stock (assuming conversion, exercise and exchange of all securities convertible into or exercisable or exchangeable for Common Stock) from such prohibitions, (2) (a) if the release or waiver is effected solely to permit a transfer not involving a disposition for value and (b) the transferee has agreed in writing to be bound by the same terms described in this lock-up letter to the extent and for the duration that such terms remain in effect at the time of the transfer, or (3) if the release or waiver is granted to a holder of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock in connection with a follow-on public offering of such Securities pursuant to a registration statement on Form S-1 that is filed with the Securities and Exchange Commission. In the event that any percentage of such Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock released from the prohibitions set forth in this lock-up letter are subject to any restrictions of the type set forth in the second paragraph of this lock-up letter, the same restrictions shall be applicable to the release of the same percentage of the undersigned's Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock. In the event that, as a result of this paragraph, any Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock held by the undersigned are released from the restrictions imposed by this lock-up letter, Morgan Stanley and Credit Suisse shall use commercially reasonable efforts to notify the Company within two business day of the effective date of such release, and the Company, in turn, in consultation with Morgan Stanley and Credit Suisse, shall use commercially reasonable efforts to notify the undersigned within two business days thereafter that the same percentage of aggregate Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock held by the undersigned has been released; provided that the failure to give such notice to the Company or the undersigned shall not give rise to any claim or liability against the Company or the Underwriters, including the Representatives.

The undersigned understands that the Company and the Underwriters are relying upon this agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

This agreement (and for the avoidance of doubt, the Restricted Period described herein) and related restrictions shall automatically terminate upon the earliest to occur, if any, of (i) the Representatives, on behalf of the Underwriters, on the one hand, or the Company, on the other hand, advising the other in writing prior to the execution of the Underwriting Agreement that they have or it has determined not to proceed with the Public Offering, (ii) the termination of the Underwriting Agreement before the sale of any Shares to the Underwriters, (iii) the registration statement filed with the SEC with respect to the Public Offering is withdrawn or (iv) June 1, 2014, in the event the closing of the Public Offering shall not have occurred on or before such date.

Whether or not the Public Offering actually occurs depends on a number of factors, including market conditions. Any Public Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

Very truly yours,

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(Print Name)

---

(Signature)

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(Address)



FORM OF WAIVER OF LOCK-UP

, 20

[Name and Address of  
Officer or Director  
Requesting Waiver]

Dear Mr./Ms. [Name]:

This letter is being delivered to you in connection with the offering by Akebia Therapeutics, Inc. (the “**Company**”) of \_\_\_\_\_ shares of common stock, par value \$ \_\_\_\_\_ per share (the “**Common Stock**”), of the Company and the lock-up letter dated \_\_\_\_\_, 20\_\_\_\_ (the “**Lock-up Letter**”), executed by you in connection with such offering, and your request for a [waiver] [release] dated \_\_\_\_\_, 20\_\_\_\_, with respect to \_\_\_\_\_ shares of Common Stock (the “**Shares**”).

The undersigned hereby agree to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Shares, effective \_\_\_\_\_, 20\_\_\_\_; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Very truly yours,

Morgan Stanley & Co. LLC  
Credit Suisse Securities (USA) LLC  
Acting severally on behalf of themselves and the several  
Underwriters named in Schedule I to the Underwriting  
Agreement

By: \_\_\_\_\_  
Name:  
Title:

cc: Company

**FORM OF PRESS RELEASE**

Akebia Therapeutics, Inc.  
[Date]

Akebia Therapeutics, Inc. (the “**Company**”) announced today that Morgan Stanley & Co. LLC and Credit Suisse Securities (USA) LLC, the joint book-running managers in the Company’s recent public sale of \_\_\_\_\_ shares of common stock is [waiving][releasing] a lock-up restriction with respect to \_\_\_\_\_ shares of the Company’s common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver][release] will take effect on \_\_\_\_\_, 20\_\_\_\_, and the shares may be sold on or after such date.

**This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.**

**AKEBIA THERAPEUTICS, INC.****Ninth Amended and Restated Certificate of Incorporation**

Pursuant to Sections 242 and 245 of the General Corporation Law of the State of Delaware, Akebia Therapeutics, Inc. has adopted this Ninth Amended and Restated Certificate of Incorporation restating, integrating and further amending its Amended and Restated Certificate of Incorporation (originally filed on February 27, 2007, under the name “Akebia Therapeutics, Inc.,” and as amended and restated on September 4, 2007, January 23, 2008, July 16, 2009, June 4, 2010, April 6, 2011, July 9, 2012, March 21, 2013 and May 10, 2013) which Ninth Amended and Restated Certificate of Incorporation has been duly proposed by the directors and adopted by the stockholders of this corporation (by written consent pursuant to Section 228 of the General Corporation Law of the State of Delaware) in accordance with the provisions of Sections 242 and 245 of the General Corporation Law of the State of Delaware.

## ARTICLE I — NAME

The name of the corporation is Akebia Therapeutics, Inc. (the “Corporation”).

## ARTICLE II — REGISTERED OFFICE AND AGENT

The address of the Corporation’s registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street in the City of Wilmington, County of New Castle, Delaware 19801, and the name of its registered agent at such address is The Corporation Trust Company.

## ARTICLE III — PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the “DGCL”).

## ARTICLE IV — CAPITALIZATION

(a) Authorized Shares. The total number of shares of stock which the Corporation shall have authority to issue is 200,000,000, consisting of (i) 175,000,000 shares of Common Stock, par value \$0.00001 per share (“Common Stock”), and (ii) 25,000,000 shares of Preferred Stock, par value \$0.00001 per share (“Preferred Stock”). Such stock may be issued from time to time by the Corporation for such consideration as may be fixed by the board of directors of the Corporation (the “Board of Directors”).

(b) Common Stock. Subject to the powers, preferences and rights of any Preferred Stock, including any series thereof, having any preference or priority over, or rights superior to, the Common Stock and except as otherwise provided by law and this Article IV, the holders of the Common Stock shall have and possess all powers and voting and other rights pertaining to the stock of the Corporation.

(i) *Voting*. Each holder of Common Stock, as such, shall be entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote; provided, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Certificate of Incorporation (including, but not limited to, any certificate of designations relating to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including, but not limited to, any certificate of designations relating to any series of Preferred Stock) or pursuant to the DGCL. There shall be no cumulative voting.

(ii) *Dividends*. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend rights of any then outstanding Preferred Stock. Except as otherwise provided by the DGCL or this Certificate of Incorporation, the holders of record of Common Stock shall share ratably in all dividends payable in cash, stock or otherwise and other distributions, whether in respect of liquidation or dissolution (voluntary or involuntary) or otherwise.

(iii) *No Preemptive Rights*. The holders of the Common Stock shall have no preemptive rights to subscribe for any shares of any class of stock of the Corporation whether now or hereafter authorized.

(iv) *No Conversion Rights*. The Common Stock shall not be convertible into, or exchangeable for, shares of any other class or classes or of any other series of the same class of the Corporation's capital stock.

(v) *Liquidation Rights*. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of Common Stock will be entitled to receive all assets of the Corporation available for distribution to its stockholders, subject to any preferential rights of any then outstanding Preferred Stock. A merger or consolidation of the Corporation with or into any other corporation or other entity or a sale or conveyance of all or any part of the assets of the Corporation, in any such case which shall not in fact result in the liquidation of the Corporation and the distribution of assets to its stockholders, shall not be deemed to be a voluntary or involuntary liquidation or dissolution or winding up of the Corporation within the meaning of this Article IV(b)(v).

(c) Preferred Stock. Shares of Preferred Stock may be issued in one or more series, from time to time, with each such series to consist of such number of shares and to have such voting powers relative to other classes or series of Preferred Stock, if any, or Common Stock, full or limited or no voting powers, and such designations, preferences and relative, participating,

optional or other special rights, and the qualifications, limitations or restrictions thereof, as shall be stated in the resolution or resolutions providing for the issuance of such series adopted by the Board of Directors, and the Board of Directors is hereby expressly vested with the authority, to the full extent now or hereafter provided by applicable law, to adopt any such resolution or resolutions. Except as otherwise provided in this Certificate of Incorporation, no vote of the holders of the Preferred Stock or Common Stock shall be a prerequisite to the designation or issuance of any shares of any series of the Preferred Stock authorized by and complying with the conditions of this Certificate of Incorporation, the right to have such vote being expressly waived by all present and future holders of the capital stock of the Corporation. Any shares of Preferred Stock that are redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law or this Certificate of Incorporation. Different series of Preferred Stock shall not be construed to constitute different classes of shares for the purposes of voting by classes unless expressly provided in the resolution or resolutions providing for the issue of such series adopted by the Board of Directors.

(d) No Class Vote On Changes In Authorized Number of Shares Of Preferred Stock. Subject to the special rights of the holders of any series of Preferred Stock pursuant to the terms of this Certificate of Incorporation, any certificate of designations or any resolution or resolutions providing for the issuance of such series of stock adopted by the Board of Directors, the number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the voting power of the outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, irrespective of the provisions of Section 242(b)(2) of the DGCL.

#### ARTICLE V — BOARD OF DIRECTORS

(a) Number of Directors; Vacancies and Newly Created Directorships. Subject to the special rights of the holders of any series of Preferred Stock to elect directors, the number of directors which shall constitute the Board of Directors shall be fixed exclusively by the Board of Directors from time to time in accordance with the Bylaws. Vacancies and newly-created directorships shall be filled exclusively by vote of a majority of the directors then in office, even if less than a quorum, or by a sole remaining director. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director. A director elected to fill a vacancy shall be elected for the unexpired term of his or her predecessor in office, and a director chosen to fill a position resulting from an increase in the number of directors shall hold office until the next election of the class for which such director shall have been chosen, subject to the election and qualification of his or her successor and to his or her earlier death, resignation or removal.

(b) Classified Board of Directors. At all meetings of stockholders for the election of directors at which a quorum is present, the directors shall be elected by a plurality of the votes cast by the holders of shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. Subject to the special rights of the holders of any series of Preferred Stock to elect directors, the Board of Directors (other than those directors elected by the holders of any series of Preferred Stock) shall be classified into three classes.

Each class shall consist, as nearly as possible, of one-third of the total number of directors constituting the entire Board of Directors and the allocation of directors among the three classes shall be determined by the Board of Directors. The initial Class I Directors shall serve for a term expiring at the first annual meeting of stockholders of the Corporation following the filing of this Certificate of Incorporation; the initial Class II Directors shall serve for a term expiring at the second annual meeting of stockholders following the filing of this Certificate of Incorporation; and the initial Class III Directors shall serve for a term expiring at the third annual meeting of stockholders following the filing of this Certificate of Incorporation. Each director in each class shall hold office until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. At each annual meeting of stockholders beginning with the first annual meeting of stockholders following the filing of this Certificate of Incorporation, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual meeting of stockholders to be held in the third year following the year of their election, with each director in each such class to hold office until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. If the number of directors is changed, any increase or decrease shall be apportioned among the classes so as to maintain the number of directors in each class as nearly equal as possible and such apportionment shall be determined by the Board of Directors.

(c) Removal. Subject to the special rights of the holders of any series of Preferred Stock to elect directors, the directors of the Corporation may be removed only for cause by the affirmative vote of the holders of at least seventy-five percent (75%) of the voting power of the outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose.

#### ARTICLE VI — LIMITATION OF DIRECTOR LIABILITY

To the fullest extent that the DGCL or any other law of the State of Delaware (as they exist on the date hereof or as they may hereafter be amended) permits the limitation or elimination of the liability of directors, no director of the Corporation shall be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. No amendment to, or modification or repeal of, this Article VI shall adversely affect any right or protection of a director of the Corporation existing hereunder with respect to any state of facts existing or act or omission occurring, or any cause of action, suit or claim that, but for this Article VI, would accrue or arise, prior to such amendment, modification or repeal. If the DGCL is amended after the date of filing this Restated Certificate of Incorporation to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL, as so amended.

#### ARTICLE VII — MEETINGS OF STOCKHOLDERS

(a) No Action by Written Consent. Except as otherwise provided for by any resolution of the Board of Directors providing for the issuance of any series of Preferred Stock, any action required or permitted to be taken by the stockholders of the Corporation may be effected only at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

(b) Special Meetings of Stockholders. Subject to any special rights of the holders of any series of Preferred Stock, and to the requirements of applicable law, special meetings of stockholders of the Corporation may be called only by or at the direction of the Board of Directors pursuant to a resolution adopted by a majority of the total number of directors which the Corporation would have if there were no vacancies. Any business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

(c) Advance Notice. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

(d) Election of Directors by Written Ballot. Election of directors need not be by written ballot.

#### ARTICLE VIII — AMENDMENTS TO THE CERTIFICATE OF INCORPORATION AND BYLAWS

(a) Bylaws. In furtherance and not in limitation of the powers conferred by law, the Board of Directors is expressly authorized to make, alter, amend or repeal the bylaws of the Corporation subject to the power of the stockholders of the Corporation entitled to vote with respect thereto to make, alter, amend or repeal the bylaws; provided, that with respect to the powers of stockholders entitled to vote with respect thereto to make, alter, amend or repeal the bylaws, in addition to any other vote otherwise required by law, the affirmative vote of the holders of at least seventy-five percent (75%) of the voting power of the outstanding shares of capital stock of the Corporation entitled to vote with respect thereto, voting together as a single class, shall be required to make, alter, amend or repeal the bylaws of the Corporation.

(b) Amendments to the Certificate of Incorporation. The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by the DGCL, and all rights conferred upon stockholders herein are granted subject to this reservation. Notwithstanding anything to the contrary contained in this Certificate of Incorporation, and notwithstanding that a lesser percentage may be permitted from time to time by applicable law, no provision of Article IV paragraph (a) (but only to the extent that such amendment would decrease the number of authorized shares of Common Stock or Preferred Stock), paragraph (c) or paragraph (d), Article V, Article VI, Article VII, Article VIII or Article IX may be altered, amended or repealed in any respect, nor may any provision or bylaw inconsistent therewith be adopted, unless in addition to any other vote required by this Certificate of Incorporation or otherwise required by law, such alteration, amendment, repeal or adoption is approved by, in addition to any other vote otherwise required by law, the affirmative vote of the holders of at least seventy-five (75%) of the voting power of the outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose.

ARTICLE IX — EXCLUSIVE JURISDICTION FOR CERTAIN ACTIONS

Unless the Corporation, as authorized by the Board of Directors, consents in writing to the selection of one or more alternative forums, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for a stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation arising pursuant to any provision of the DGCL or this Certificate of Incorporation or the Corporation's Bylaws or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv), any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation (including, without limitation, shares of Common Stock) shall, and shall be deemed to, have notice of and to have consented to the provisions of this Article IX.

ARTICLE X — SEVERABILITY

If any provision or provisions of this Certificate of Incorporation shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever: (i) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Certificate of Incorporation (including, without limitation, each portion of any paragraph of this Certificate of Incorporation containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (ii) to the fullest extent possible, the provisions of this Certificate of Incorporation (including, without limitation, each such portion of any paragraph of this Certificate of Incorporation containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to permit the Corporation to protect its directors, officers, employees and agents from personal liability in respect of their good faith service to or for the benefit of the Corporation to the fullest extent permitted by law.



ARTICLE XI — EFFECTIVENESS

This Restated Certificate of Incorporation is to become effective at [12:00 p.m.] on [ ], 2014.

\* \* \*

IN WITNESS WHEREOF, the undersigned has caused this Seventh Restated Certificate of Incorporation to be executed by the officer below this \_\_\_\_\_ day of \_\_\_\_\_, 2014.

AKEBIA THERAPEUTICS, INC.

By: \_\_\_\_\_  
Name: John P. Butler  
Title: Chief Executive Officer and President

*Signature Page to Restated Certificate of Incorporation*

## AMENDED AND RESTATED BYLAWS

## OF

## AKEBIA THERAPEUTICS, INC.

## SECTION 1 - STOCKHOLDERS

Section 1.1. Annual Meeting.

An annual meeting of the stockholders of Akebia Therapeutics, Inc., a Delaware corporation (the "Corporation") for the election of directors to succeed those whose term expire and for the transaction of such other business as may properly come before the meeting shall be held at the place, if any, within or without the State of Delaware, on the date and at the time that the Board of Directors of the Corporation (the "Board of Directors") shall each year fix. Unless stated otherwise in the notice of the annual meeting of the stockholders of the Corporation, such annual meeting shall be at the principal office of the Corporation.

Section 1.2. Advance Notice of Proposals of Business and Nominations.(a) Business at Annual Meetings of Stockholders

- (1) Proposals for business (other than nominations of persons for election to the Board of Directors, which must be made in compliance with and are governed exclusively by Section 1.2(b) hereto) to be transacted by the stockholders at an annual meeting of stockholders may be made (i) pursuant to the Corporation's notice with respect to such meeting (or any supplement thereto), (ii) by or at the direction of the Board of Directors or any committee thereof or (iii) by any stockholder of record of the Corporation who (A) was a stockholder of record at the time of the giving of the notice contemplated in Section 1.2(a), (B) is entitled to vote at such meeting and (C) has complied with the notice procedures set forth in this Section 1.2. Except as otherwise required by law, clause (iii) of this Section 1.2(a)(1) shall be the exclusive means for a stockholder to propose business (other than nominations and proposals properly brought pursuant to applicable provisions of federal law, including the Securities Exchange Act of 1934 (as amended from time to time, the "Act") and the rules and regulations thereunder) before an annual meeting of stockholders.
- (2) Except as otherwise required by law, for proposals (other than nominations of persons for election to the Board of Directors, which must be made in compliance with and are governed exclusively by Section 1.2(b) hereto) to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of

Section 1.2(a)(1), (i) the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation with the information contemplated by Section 1.2(a)(3), and (ii) the business must be a proper matter for stockholder action under the General Corporation Law of the State of Delaware (the “DGCL”). The notice requirements of this Section 1.2(a) shall be deemed satisfied by a stockholder with respect to business other than a nomination if the stockholder has notified the Corporation of his, her or its intention to present a proposal at an annual meeting in compliance with applicable rules and regulations promulgated under the Act and such stockholder’s proposal has been included in a proxy statement prepared by the Corporation to solicit proxies for such annual meeting.

- (3) To be timely for purposes of Section 1.2(a), a stockholder’s notice must be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation on a date not later than the close of business on the 90<sup>th</sup> day nor earlier than the close of business on the 120<sup>th</sup> day prior to the anniversary date of the prior year’s annual meeting or, if there was no annual meeting in the prior year or if the date of the current year’s annual meeting is more than 30 days before or after the anniversary date of the prior year’s annual meeting, on or before 10 days after the day on which the date of the current year’s annual meeting is first disclosed in a public announcement. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the delivery of such notice. Such notice from a stockholder must state (i) as to each proposal that the stockholder seeks to bring before the meeting, a brief description of such proposal, the reasons for making the proposal at the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the bylaws of the Corporation, the language of the proposed amendment) and any material interest that the stockholder has in the proposal; and (ii) (A) the name and address of the stockholder giving the notice on whose behalf the proposal is made, (B) the class (and, if applicable, series) and number of shares of stock of the Corporation that are, directly or indirectly, owned beneficially or of record by the stockholder, (C) any option, warrant, convertible security, stock appreciation right or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class (or, if applicable, series) of shares of stock of the Corporation or with a value derived in whole or in part from the value of any class (or, if applicable, series) of shares of stock of the Corporation, whether or not such instrument or right shall be subject to settlement in the underlying class or series of

capital stock of the Corporation or otherwise (each, a “Derivative Instrument”) directly or indirectly owned beneficially or of record by such stockholder and any other direct or indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of stock of the Corporation of the stockholder, (D) any proxy, contract, arrangement, understanding or relationship pursuant to which such stockholder has a right to vote any securities of the Corporation, (E) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder is a general partner or beneficially owns, directly or indirectly, an interest in a general partner, (F) any performance-related fees (other than an asset-based fee) that such stockholder is entitled to based on any increase or decrease in the value of the shares of stock of the Corporation or Derivative Instruments, (G) any other information relating to such stockholder, if any, required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies for, as applicable, the proposal and/or for the election of directors in an election contest pursuant to and in accordance with Section 14(a) of the Act and the rules and regulations of the Securities and Exchange Commission thereunder, (H) a representation that the stockholder is a holder of record of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business, (I) a certification as to whether or not the stockholder has complied with all applicable federal, state and other legal requirements in connection with the stockholder’s acquisition of shares of capital stock or other securities of the Corporation and the stockholder’s acts or omissions as a stockholder (or beneficial owner of securities) of the Corporation, and (J) whether the stockholder intends to deliver a proxy statement and form of proxy to holders of at least the percentage of the Corporation’s voting shares required under applicable law to carry the proposal. The information required to be included in a notice pursuant to this Section 1.2(a)(3) shall be provided as of the date of such notice. The information required to be included in a notice pursuant to this Section 1.2(a)(3) shall not include any ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is directed to prepare and submit the notice required by this Section 1.2(a)(3) on behalf of a beneficial owner of the shares held of record by such broker, dealer, commercial bank, trust company or other nominee and who is not otherwise affiliated or associated with such beneficial owner.

- (4) Notwithstanding anything in these bylaws to the contrary, no business (other than nominations of persons for election to the

Board of Directors, which must be made in compliance with and are governed exclusively by Section 1(b) hereto) shall be conducted at an annual meeting except in accordance with the procedures set forth in this Section 1.2(a).

(b) Nominations at Annual Meetings of Stockholders

- (1) Nominations of persons for election to the Board of Directors at an annual meeting of stockholders may be made (i) pursuant to the Corporation's notice with respect to such meeting (or any supplement thereto), (ii) by or at the direction of the Board of Directors or any committee thereof or (iii) by any stockholder of record of the Corporation who (A) was a stockholder of record at the time of the giving of the notice contemplated in Section 1.2(b), (B) is entitled to vote at such meeting and (C) has complied with the notice procedures set forth in this Section 1.2(b). Except as otherwise required by law, clause (iii) of this Section 1.2(b) shall be the exclusive means for a stockholder to make nominations of persons for election to the Board of Directors before an annual meeting of stockholders. Except as otherwise required by law, for nominations to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 1.2(b)(1), the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation with the information contemplated by Section 1.2(b)(2).
- (2) To be timely for purposes of Section 1.2(b), a stockholder's notice must be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation on a date not later than the close of business on the 90<sup>th</sup> day nor earlier than the close of business on the 120<sup>th</sup> day prior to the anniversary date of the prior year's annual meeting or, if there was no annual meeting in the prior year or if the date of the current year's annual meeting is more than 30 days before or after the anniversary date of the prior year's annual meeting, on or before 10 days after the day on which the date of the current year's annual meeting is first disclosed in a public announcement. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the delivery of such notice. Such notice from a stockholder must state (i) as to each nominee that the stockholder proposes for election or reelection as a director, (A) all information relating to such nominee that would be required to be disclosed in solicitations of proxies for the election of such nominee as a director pursuant to Regulation 14A under the Act and such nominee's written consent to serve as a director if elected, and (B) a description of all direct and indirect compensation and other material monetary arrangements,

agreements or understandings during the past three years, and any other material relationship, if any, between or concerning such stockholder, or any of their respective affiliates or associates, on the one hand, and the proposed nominee or any of his or her affiliates or associates, on the other hand; and (ii) (A) the name and address of the stockholder giving the notice on whose behalf the nomination is made, (B) the class (and, if applicable, series) and number of shares of stock of the Corporation that are, directly or indirectly, owned beneficially or of record by the stockholder, (C) any option, warrant, convertible security, stock appreciation right or similar right with an exercise or conversion privilege or a settlement payment or mechanism at a price related to any class (or, if applicable, series) of shares of stock of the Corporation or a Derivative Instrument directly or indirectly owned beneficially or of record by such stockholder and any other direct or indirect opportunity to profit or share in any profit derived from any increase or decrease in the value of shares of stock of the Corporation of the stockholder, (D) any proxy, contract, arrangement, understanding or relationship pursuant to which such stockholder has a right to vote any securities of the Corporation, (E) any proportionate interest in shares of the Corporation or Derivative Instruments held, directly or indirectly, by a general or limited partnership in which such stockholder is a general partner or beneficially owns, directly or indirectly, an interest in a general partner, (F) any performance-related fees (other than an asset-based fee) that such stockholder is entitled to based on any increase or decrease in the value of the shares of stock of the Corporation or Derivative Instruments, (G) any other information relating to such stockholder, if any, required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies for the election of directors in an election contest pursuant to and in accordance with Section 14(a) of the Act and the rules and regulations of the Securities and Exchange Commission thereunder, (H) a representation that the stockholder is a holder of record of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such nomination, (I) a certification as to whether or not the stockholder has complied with all applicable federal, state and other legal requirements in connection with the stockholder's acquisition of shares of capital stock or other securities of the Corporation and the stockholder's acts or omissions as a stockholder (or beneficial owner of securities) of the Corporation, and (J) whether the stockholder intends to deliver a proxy statement and form of proxy to holders of a sufficient number of holders of the Corporation's voting shares reasonably believed by such stockholder to be sufficient to elect such nominee

or nominees or otherwise to solicit proxies or votes from stockholders in support of such nomination. The Corporation may require any proposed nominee to furnish such other information as may be reasonably requested by the Corporation to determine the eligibility of the proposed nominee to serve as an independent director of the Corporation or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of the nominee. The information required to be included in a notice pursuant to this Section 1.2(b)(2) shall be provided as of the date of such notice. The information required to be included in a notice pursuant to this Section 1.2(b)(2) shall not include any ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is directed to prepare and submit the notice required by this Section 1.2(b)(2) on behalf of a beneficial owner of the shares held of record by such broker, dealer, commercial bank, trust company or other nominee and who is not otherwise affiliated or associated with such beneficial owner.

(c) Subject to the certificate of incorporation of the Corporation (the "Certificate of Incorporation") and applicable law, only persons nominated in accordance with procedures stated in this Section 1.2(b) shall be eligible for election as and to serve as members of the Board of Directors and the only business that shall be conducted at an annual meeting of stockholders is the business that has been brought before the meeting in accordance with the procedures set forth in this Section 1.2(a). The chairman of the meeting shall have the power and the duty to determine whether a nomination or any proposal has been made according to the procedures stated in this Section 1.2 and, if any nomination or proposal does not comply with this Section 1.2, unless otherwise required by law, the nomination or proposal shall be disregarded.

(d) For purposes of this Section 1.2, "public announcement" means disclosure in a press release reported by the Dow Jones News Service, Associated Press or a comparable news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Act.

(e) Notwithstanding the foregoing provisions of this Section 1.2, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or proposed business or does not provide the information required by Section 1.2(a) or 1.2(b), including any required supplement thereto, such nomination may be disregarded and such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 1.2, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders.



(f) Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of meeting. Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected pursuant to the Corporation's notice of meeting. Such nominations may be made (1) by or at the direction of the Board of Directors or any committee thereof or (2) provided that the Board of Directors has determined that directors shall be elected at such meeting, by any stockholder of the Corporation who (A) is a stockholder of record at the time the notice provided for in this Section 1.2(f) is delivered to the Secretary of the Corporation, (B) is entitled to vote at the meeting, and (C) complies with the notice procedures set forth in Section 1.2(b). In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any such stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the Corporation's notice of meeting, if the stockholder's notice required by paragraph (f) of this Section 1.2 shall be delivered to the Secretary of the Corporation at the principal executive offices of the Corporation not earlier than the close of business on the 120<sup>th</sup> day prior to such special meeting and not later than the close of business on the later of the 90<sup>th</sup> day prior to such special meeting or the tenth 10<sup>th</sup> day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting. In no event shall the public announcement of an adjournment or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(g) Any stockholder who submits a notice of proposal for business or nomination for election pursuant to this Section 1.2 is required to update and supplement the information disclosed in such notice, if necessary, so that the information provided or required to be provided in such notice shall be true and correct as of the record date for determining the stockholders entitled to notice of the meeting of stockholders and as of the date that is 10 business days prior to such meeting of the stockholders or any adjournment or postponement thereof, and such update and supplement shall be received by the Secretary at the principal executive offices of the Corporation not later than the close of business on the fifth business day after the record date for the meeting of stockholders (in the case of the update and supplement required to be made as of the record date), and not later than the close of business on the eighth business day prior to the date for the meeting of stockholders or any adjournment or postponement thereof (in the case of the update and supplement required to be made as of 10 business days prior to the meeting of stockholders or any adjournment or postponement thereof).

(h) To be qualified to be a nominee for election or re-election as a director of the Corporation, a person must deliver (in the case of a person nominated by a stockholder in accordance with Section 1(b) or 1(f), in accordance with the time periods prescribed for delivery of notice under such sections) to the Secretary at the principal executive offices of the Corporation a written questionnaire with respect to the background and qualification of such person and the background of any other person or entity on whose behalf the nomination is being

made (which questionnaire shall be provided by the Secretary upon written request) and a written representation and agreement (in the form provided by the Secretary upon written request) that such person (i) is not and will not become a party to (A) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the Corporation, will act or vote on any issue or question (a "Voting Commitment") that has not been disclosed to the Corporation or (B) any Voting Commitment that could limit or interfere with such person's ability to comply, if elected as a director of the Corporation, with such person's fiduciary duties under applicable law, (ii) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director that has not been disclosed therein and (iii) would be in compliance, and if elected as a director of the Corporation will comply, with all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation. The Corporation may also require any proposed nominee to furnish such other information as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve either as a director of the Corporation or as an independent director of the Corporation under applicable Securities and Exchange Commission and stock exchange rules and the Corporation's publicly disclosed corporate governance guidelines, or that could be material to a reasonable stockholder's understanding of the qualifications and/or independence, or lack thereof, of such nominee.

(i) Notwithstanding the foregoing provisions of these bylaws, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations promulgated thereunder with respect to the matters set forth in these bylaws; provided, however, that any references in these bylaws to the Exchange Act or the rules and regulations promulgated thereunder are not intended to and shall not limit the requirements applicable to any nomination or other business to be considered pursuant to this Section 1.2.

#### Section 1.3. Special Meetings; Notice.

Special meetings of the stockholders of the Corporation may be called only in the manner set forth in the Certificate of Incorporation. Notice of every special meeting of the stockholders of the Corporation shall state the purpose or purposes of such meeting. Except as otherwise required by law, the business conducted at a special meeting of stockholders of the Corporation shall be limited exclusively to the business set forth in the Corporation's notice of meeting, and the individual or group calling such meeting shall have exclusive authority to determine the business included in such notice.

#### Section 1.4. Notice of Meetings.

Notice of the place, date and time of all meetings of stockholders of the Corporation, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting) and the means of remote communications, if any, by which stockholders and proxy holders may be deemed present and vote at such meeting, and, in the case of all special meetings of stockholders, the purpose or purposes of the meeting, shall be given not less than 10 nor more than 60 days before the date on which such meeting is to be held, to each stockholder entitled to notice of the meeting.

The Corporation may postpone or cancel any previously called annual or special meeting of stockholders of the Corporation by making a public announcement (as defined in Section 1.2(d)) of such postponement or cancellation prior to the meeting. When a previously called annual or special meeting is postponed to another time, date or place, notice of the place, date and time of the postponed meeting, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting) and the means of remote communications, if any, by which stockholders and proxy holders may be deemed present and vote at such postponed meeting, shall be given in conformity with this Section 1.4 unless such meeting is postponed to a date that is not more than 60 days after the date that the initial notice of the meeting was provided in conformity with this Section 1.4.

When a meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if the time and place thereof and the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; provided, however, that if the adjournment is for more than 30 days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting or, if after the adjournment a new record date for stockholders entitled to vote is fixed for the adjourned meeting, the Board of Directors shall fix a new record date for notice of such adjourned meeting in conformity herewith and such notice shall be given to each stockholder of record entitled to vote at such adjourned meeting as of the record date for notice of such adjourned meeting. At any adjourned meeting, any business may be transacted that may have been transacted at the original meeting.

#### Section 1.5. Quorum.

At any meeting of the stockholders, the holders of shares of stock of the Corporation entitled to cast a majority of the total votes entitled to be cast by the holders of all outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors (“Voting Stock”), present in person or by proxy, shall constitute a quorum for all purposes, unless or except to the extent that the presence of a larger number is required by applicable law or the Certificate of Incorporation. If a separate vote by one or more classes or series is required, the holders of shares entitled to cast a majority of the total votes entitled to be cast by the holders of the shares of the class or classes or series, present in person or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter. If a quorum shall fail to attend any meeting, the chairman of the meeting may adjourn the meeting to another place, date and time.

#### Section 1.6. Organization.

The chairman of the Board or, in his or her absence, the person whom the Board of Directors designates or, in the absence of that person or the failure of the Board of Directors to designate a person, the President of the Corporation or, in his or her absence, the person chosen

by the holders of a majority of the shares of capital stock entitled to vote who are present, in person or by proxy, shall call to order any meeting of the stockholders of the Corporation and act as chairman of the meeting. In the absence of the Secretary or any Assistant Secretary of the Corporation, the secretary of the meeting shall be the person the chairman appoints.

Section 1.7. Conduct of Business.

The chairman of any meeting of stockholders of the Corporation shall determine the order of business and the rules of procedure for the conduct of such meeting, including the manner of voting and the conduct of discussion as he or she determines to be in order. The chairman shall have the power to adjourn the meeting to another place, date and time. The date and time of the opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the meeting. Except to the extent inconsistent with such rules and regulations as adopted by the Board of Directors, the chairman of the meeting shall have the right and authority to convene and (for any or no reason) to adjourn the meeting, to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board of Directors or prescribed by the chairman of the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present; (iii) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the chairman of the meeting shall determine; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. The chairman of the meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting, shall, if the facts warrant, determine and declare to the meeting that a nomination or matter of business was not properly brought before the meeting and if such chairman should so determine, such chairman shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered.

Section 1.8. Proxies; Inspectors.

(a) At any meeting of the stockholders, every stockholder entitled to vote may vote in person or by proxy authorized by an instrument in writing or by a transmission permitted by applicable law.

(b) Prior to a meeting of the stockholders of the Corporation, the Corporation shall appoint one or more inspectors to act at a meeting of stockholders of the Corporation and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If no inspector or alternate is able to act at a meeting of stockholders, the person presiding at the meeting may, and to the extent required by applicable law, shall, appoint one or more inspectors to act at the meeting. Each inspector, before beginning the discharge of his or her duties, shall take and sign an oath faithfully to execute the duties of inspector with strict impartiality and according to the best of his or her ability. The inspectors may appoint or retain other persons or entities to assist the inspectors in the performance of the duties of inspectors. The inspectors shall have the duties prescribed by applicable law.

Section 1.9. Voting.

Except as otherwise required by the rules or regulations of any stock exchange applicable to the Corporation or pursuant to any law or regulation applicable to the Corporation or by the Certificate of Incorporation or these bylaws, all matters other than the election of directors shall be determined by a majority of the votes cast on the matter affirmatively or negatively. All elections of directors shall be determined by a plurality of the votes cast.

Section 1.10. Action by Written Consent.

Except as otherwise may be provided in the Certificate of Incorporation, stockholders may not take any action by written consent in lieu of a meeting of stockholders.

Section 1.11. Stock List.

A complete list of stockholders of the Corporation entitled to vote at any meeting of stockholders of the Corporation, arranged in alphabetical order for each class of stock and showing the address of each such stockholder and the number of shares registered in the name of such stockholder, shall be open to the examination of any such stockholder, for any purpose germane to a meeting of the stockholders of the Corporation, for a period of at least 10 days before the meeting (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting or (ii) during ordinary business hours at the principal place of business of the Corporation; provided, however, if the record date for determining the stockholders entitled to vote is less than 10 days before the meeting date, the list shall reflect the stockholders entitled to vote as of the 10th day before such meeting date. If the meeting is to be held at a place, then a list of stockholders entitled to vote at the meeting shall be produced and kept at the time and place of the meeting during the whole time thereof and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

Except as otherwise provided by law, the stock ledger shall be the sole evidence of the identity of the stockholders entitled to vote at a meeting and the number of shares held by each stockholder.

## SECTION 2 - BOARD OF DIRECTORS

Section 2.1. General Powers and Qualifications of Directors.

The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. In addition to the powers and authorities these bylaws expressly confer upon them, the Board of Directors may exercise all such powers of the Corporation and do all such lawful acts and things as are not by the DGCL or by the Certificate of Incorporation or by these bylaws required to be exercised or done by the stockholders. Directors need not be stockholders of the Corporation to be qualified for election or service as a director of the Corporation.

Section 2.2. Number of Directors.

The number of directors constituting the Board of Directors shall be seven (7). Subject to the special rights of the holders of any series of Preferred Stock to elect directors, the number of directors which shall constitute the Board of Directors may be increased or decreased exclusively by the Board of Directors from time to time by resolution adopted by the affirmative vote of at least a majority of the directors then in office.

Section 2.3. Regular Meetings.

Regular meetings of the Board of Directors shall be held at the place, on the date and at the time as shall have been established by the Board of Directors and publicized among all directors. A notice of a regular meeting, the date of which has been so publicized, shall not be required.

Section 2.4. Special Meetings.

Special meetings of the Board of Directors may be called by the Chairman, President or by two or more directors then in office. Notice of the place, if any, date and time of each special meeting shall be given to each director either (a) by mailing written notice thereof not less than five days before the meeting, or (b) by telephone, facsimile or other means of electronic transmission providing notice thereof not less than twenty-four hours before the meeting. A meeting may be held at any time without notice if all the directors are present (except as otherwise provided by law) or if those not present waive notice of the meeting in writing, either before or after such meeting. Any and all business may be transacted at a special meeting of the Board of Directors.

Section 2.5. Quorum.

At any meeting of the Board of Directors, a majority of the total number of directors then in office shall constitute a quorum for all purposes. If a quorum shall fail to attend any meeting, a majority of those present may adjourn the meeting to another place, date or time, without further notice or waiver thereof.

Section 2.6. Participation in Meetings By Conference Telephone or Other Communications Equipment.

Members of the Board of Directors, or of any committee thereof, may participate in a meeting of the Board of Directors or committee thereof by means of conference telephone or other communications equipment by means of which all directors participating in the meeting can hear each other director, and such participation shall constitute presence in person at the meeting.

Section 2.7. Conduct of Business.

At any meeting of the Board of Directors, business shall be transacted in the order and manner that the Board of Directors may from time to time determine, and all matters shall be determined by the vote of a majority of the directors present, provided a quorum is present at the

time such matter is acted upon, except as otherwise provided in the Certificate of Incorporation or these bylaws or required by applicable law. The Board of Directors or any committee thereof may take action without a meeting if all members thereof consent thereto in writing or by electronic transmission, and the writing or writings, or electronic transmission or electronic transmissions, are filed with the minutes of proceedings of the Board of Directors or any committee thereof. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

Section 2.8. Chairman of the Board.

The Board of Directors may elect or remove, by the affirmative vote of at least a majority of the directors then in office, a Chairman. Any Chairman must be a director of the Corporation and must not be an officer or employee of the Corporation. The Chairman shall preside at all meetings of the Board of Directors and at all meetings of the stockholders and, subject to the provisions of these Bylaws and the direction of the Board of Directors, the Chairman shall have such powers and perform such duties that are commonly incident to the position of chairman of the board or as may be prescribed from time to time by the Board of Directors or provided in these Bylaws.

Section 2.9. Compensation of Directors.

The Board of Directors shall be authorized to fix the compensation of directors. The directors of the Corporation shall be paid their expenses, if any, of attendance at each meeting of the Board of Directors and may be reimbursed a fixed sum for attendance at each meeting of the Board of Directors, paid an annual retainer or paid other compensation, including equity compensation, as the Board of Directors determines. No such payment shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor. Members of committees shall have their expenses, if any, of attendance of each meeting of such committee reimbursed and may be paid compensation for attending committee meetings or being a member of a committee.

**SECTION 3 - COMMITTEES**

Section 3.1. Committees of the Board of Directors.

The Board of Directors may designate committees of the Board of Directors, with such lawfully delegable powers and duties as it thereby confers, to serve at the pleasure of the Board of Directors and shall, for those committees, appoint a director or directors to serve as the member or members, designating, if it desires, other directors as alternate members who may replace any absent or disqualified member at any meeting of such committee. Such designations and appointments shall be determined by the vote of a majority of directors present at a meeting such matters are acted upon in accordance with Section 2.7; *provided, however*, that the chairperson of each committee shall be appointed, and may only be removed, with or without cause, by the affirmative vote of at least a majority of the directors then in office.

## SECTION 4 - OFFICERS

### Section 4.1. Generally.

The officers of the Corporation shall consist of a President and Chief Executive Officer, one or more Senior Vice Presidents, one or more Vice Presidents, a Secretary, one or more Assistant Secretaries, a Treasurer, one or more Assistant Treasurers, a Chief Financial Officer and other officers as may from time to time be appointed by the Board of Directors. Each officer shall hold office until his or her successor is elected and qualified or until his or her earlier resignation or removal. Any number of offices may be held by the same person. The compensation of officers appointed by the Board of Directors shall be determined from time to time by the Board of Directors or a committee thereof or by the officers as may be designated by resolution of the Board of Directors.

### Section 4.2. President.

Unless otherwise determined by the Board of Directors, the President shall be the Chief Executive Officer of the Corporation. Subject to the provisions of these bylaws and to the direction of the Board of Directors, he or she shall have the responsibility for the general management and control of the business and affairs of the Corporation and shall perform all duties and have all powers that are commonly incident to the office of chief executive or which are delegated to him or her by the Board of Directors. He or she shall have the power to sign all stock certificates, contracts and other instruments of the Corporation that are authorized and shall have general supervision and direction of all of the other officers, employees and agents of the Corporation.

### Section 4.3. Senior Vice Presidents and Vice Presidents.

Each Senior Vice President and Vice President shall have the powers and duties delegated to him or her by the Board of Directors or the President. One Senior Vice President may be designated by the Board of Directors to perform the duties and exercise the powers of the President in the event of the President's absence or disability.

### Section 4.4. Secretary and Assistant Secretaries.

The Secretary shall issue all authorized notices for, and shall keep minutes of, all meetings of the stockholders and the Board of Directors. He or she shall have charge of the corporate books and shall perform other duties as the Board of Directors may from time to time prescribe.

Any Assistant Secretary shall perform such duties and possess such powers as the Board of Directors, the Chief Executive Officer or the Secretary may from time to time prescribe. In the event of the absence, inability or refusal to act of the Secretary, the Assistant Secretary, (or if there shall be more than one, the Assistant Secretaries in the order determined by the Board of Directors) shall perform the duties and exercise the powers of the Secretary.

### Section 4.5. Chief Financial Officer, Treasurer and Assistant Treasurers.

The Chief Financial Officer shall keep or cause to be kept the books of account of the Corporation in a thorough and proper manner and shall render statements of the financial affairs of the Corporation in such form and as often as required by the Board of Directors or the President. The Chief Financial Officer, subject to the order of the Board of Directors, shall have



the custody of all funds and securities of the Corporation. The Chief Financial Officer shall perform other duties commonly incident to his office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time. The President may direct the Treasurer or any Assistant Treasurer to assume and perform the duties of the Chief Financial Officer in the absence or disability of the Chief Financial Officer, and each Treasurer and Assistant Treasurer shall perform other duties commonly incident to his office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

Section 4.6. Delegation of Authority.

The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

Section 4.7. Removal.

The Board of Directors may remove any officer of the Corporation at any time, with or without cause.

Section 4.8. Action with Respect to Securities of Other Companies.

Unless otherwise directed by the Board of Directors, the President, or any officer of the Corporation authorized by the President, shall have power to vote and otherwise act on behalf of the Corporation, in person or by proxy, at any meeting of stockholders or equityholders of, or with respect to any action of, stockholders or equityholders of any other entity in which the Corporation may hold securities and otherwise to exercise any and all rights and powers which the Corporation may possess by reason of its ownership of securities in such other entity.

## SECTION 5 - STOCK

Section 5.1. Certificates of Stock.

Shares of the capital stock of the Corporation may be certificated or uncertificated, as provided in the DGCL. Stock certificates shall be signed by, or in the name of the Corporation by, (i) the chairman of the Board (if any) or the vice-chairman of the Board (if any), or the President or a Senior Vice President, and (ii) the Secretary or an Assistant Secretary, or the Treasurer or an Assistant Treasurer, or the Chief Financial Officer, certifying the number of shares owned by such stockholder. Any signatures on a certificate may be by facsimile.

Section 5.2. Transfers of Stock.

Transfers of stock shall be made only upon the transfer books of the Corporation kept at an office of the Corporation (within or outside of the State of Delaware) or by transfer agents designated to transfer shares of the stock of the Corporation.

Section 5.3. Lost, Stolen or Destroyed Certificates.

In the event of the loss, theft or destruction of any certificate of stock, another may be issued in its place pursuant to regulations as the Board of Directors may establish concerning proof of the loss, theft or destruction and concerning the giving of a satisfactory bond or indemnity, if deemed appropriate.

Section 5.4. Regulations.

The issue, transfer, conversion and registration of certificates of stock of the Corporation shall be governed by other regulations as the Board of Directors may establish.

Section 5.5. Record Date.

(a) In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board of Directors so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board of Directors determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

(b) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix a record date, which shall not be more than sixty (60) days prior to such other action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

**SECTION 6 - INDEMNIFICATION AND ADVANCEMENT OF EXPENSES**

Section 6.1. Right to Indemnification and Advancement.

Each person who was or is made a party or is threatened to be made a party to or is otherwise involved (including involvement, without limitation, as a witness) in any actual or

threatened action, suit or proceeding, whether civil, criminal, administrative or investigative (a "proceeding"), by reason of the fact that he or she is or was a director or officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as an employee or agent of the Corporation or as a director, officer, partner, member, trustee, administrator, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust or other enterprise, including service with respect to an employee benefit plan (an "indemnitee"), whether the basis of such proceeding is alleged action in an official capacity as a director or officer or in any other capacity while serving as a director or officer, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than permitted prior thereto), against all expense, liability and loss (including attorneys' fees and related disbursements, judgments, fines, excise taxes, penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such indemnitee in connection therewith and such indemnification shall continue as to an indemnitee who has ceased to be a director, officer, partner, member, trustee, administrator, employee or agent and shall inure to the benefit of the indemnitee's heirs, executors and administrators; provided, however, that, except as provided in Section 6.2 with respect to proceedings to enforce rights to indemnification, the Corporation shall indemnify any such indemnitee in connection with a proceeding (or part thereof) initiated by such indemnitee only if such proceeding (or part thereof) was authorized by the Board of Directors of the Corporation. The right to indemnification conferred in this Section 6.1 shall be a contract right. In addition to the right to indemnification conferred herein, an indemnitee shall also have the right, to the fullest extent not prohibited by law, to be paid by the Corporation the expenses incurred in defending any such proceeding in advance of its final disposition (an "advance of expenses"); provided, however, that if and to the extent that the DGCL requires, an advance of expenses incurred by an indemnitee shall be made only upon delivery to the Corporation of an undertaking (an "undertaking"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such indemnitee is not entitled to be indemnified for such expenses under this Section 6.1 or otherwise. The Corporation may also, by action of its Board of Directors, provide indemnification and advancement of expenses to employees and agents of the Corporation.

#### Section 6.2. Procedure for Indemnification.

Any indemnification of a director or officer of the Corporation or advance of expenses (including attorneys' fees, costs and charges) under this Section 6.2 shall be made promptly. If a claim for indemnification pursuant to this Section 6 is not paid in full within 60 days after the Corporation has received a written request for indemnity, or a claim for the advancement of expenses is not paid in full within 30 days after the Corporation has received a statement or statements requesting such amounts to be advanced, the indemnitee shall thereupon (but not before) be entitled to file suit to recover the unpaid amount of such claim. Such person's costs and expenses incurred in connection with successfully establishing his or her right to indemnification or advancement of expense, in whole or in part, in any such action shall also be paid by the Corporation to the fullest extent permitted by Delaware law. It shall be a defense to any such action (other than an action brought to enforce a claim for the advance of expenses where the undertaking required pursuant to Section 6.1, if any, has been tendered to the

Corporation) that the claimant has not met the standards of conduct which make it permissible under the DGCL for the Corporation to indemnify the claimant for the amount claimed, but the burden of such defense shall be on the Corporation to the fullest extent permitted by law. Neither the failure of the Corporation (including its Board of Directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because he or she has met the applicable standard of conduct set forth in the DGCL, nor an actual determination by the Corporation (including its Board of Directors, independent legal counsel or its stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that the claimant has not met the applicable standard of conduct. The procedure for indemnification of other employees and agents for whom indemnification and advancement of expenses is provided pursuant to Section 6.1 shall be the same procedure set forth in this Section 6.2 for directors or officers, unless otherwise set forth in the action of the Board of Directors providing indemnification and advancement of expenses for such employee or agent.

Section 6.3. Insurance.

The Corporation may purchase and maintain insurance on its own behalf and on behalf of any person who is or was a director, officer, employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust or other enterprise against any expense, liability or loss asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expenses, liability or loss under the DGCL.

Section 6.4. Service for Subsidiaries.

Any person serving as a director, officer, employee or agent of another corporation or of a partnership, joint venture, limited liability company, trust or other enterprise, at least 50% of whose equity interests are owned by the Corporation (a "subsidiary" for this Section 6) shall be conclusively presumed to be serving in such capacity at the request of the Corporation.

Section 6.5. Reliance.

Persons who after the date of the adoption of this provision become or remain directors or officers of the Corporation or who, while a director or officer of the Corporation, become or remain a director, officer, employee or agent of a subsidiary, shall be conclusively presumed to have relied on the rights to indemnity, advance of expenses and other rights contained in this Section 6 in entering into or continuing such service.

Section 6.6. Non-Exclusivity of Rights; Continuation of Rights to Indemnification.

The rights to indemnification and to the advance of expenses conferred in this Section 6 shall not be exclusive of any other right which any person may have or hereafter acquire under the Certificate of Incorporation or under any statute, bylaw, agreement, vote of stockholders or disinterested directors or otherwise. All rights to indemnification under this Section 6 shall be

deemed to be a contract between the Corporation and each director or officer of the Corporation who serves or served in such capacity at any time while this Section 6 is in effect. Any repeal or modification of this Section 6 or any repeal or modification of relevant provisions of the DGCL or any other applicable laws shall not in any way diminish any rights to indemnification and advancement of expenses of such director or officer or the obligations of the Corporation arising hereunder with respect to any proceeding arising out of, or relating to, any actions, transactions or facts occurring prior to the final adoption of such repeal or modification.

Section 6.7. Merger or Consolidation.

For purposes of this Section 6, references to the "Corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under this Section 6 with respect to the resulting or surviving corporation as he or she would have with respect to such constituent corporation if its separate existence had continued.

Section 6.8. Savings Clause.

If this Section 6 or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify and advance expenses to each person entitled to indemnification under Section 6.1 as to all expense, liability and loss (including attorneys' fees and related disbursements, judgments, fines, ERISA excise taxes and penalties, penalties and amounts paid or to be paid in settlement) actually and reasonably incurred or suffered by such person and for which indemnification or advancement of expenses is available to such person pursuant to this Section 6 to the fullest extent permitted by any applicable portion of this Section 6 that shall not have been invalidated and to the fullest extent permitted by applicable law.

**SECTION 7 - NOTICES**

Section 7.1. Notices.

Except as otherwise provided herein or permitted by applicable law, notices to directors and stockholders shall be in writing and delivered personally, electronically or mailed to the directors or stockholders at their addresses appearing on the books of the Corporation. If mailed, notice to a stockholder of the Corporation shall be deemed given when deposited in the mail, postage prepaid, directed to a stockholder at such stockholder's address as it appears on the records of the Corporation. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders of the Corporation may be given by electronic transmission in the manner provided in Section 232 of the DGCL.

Section 7.2. Waivers.

A written waiver of any notice, signed by a stockholder or director, or a waiver by electronic transmission by such person or entity, whether given before or after the time of the event for which notice is to be given, shall be deemed equivalent to the notice required to be given to such person or entity. Neither the business nor the purpose of any meeting need be specified in the waiver. Attendance at any meeting shall constitute waiver of notice except attendance for the sole purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

**SECTION 8 - MISCELLANEOUS**

Section 8.1. Corporate Seal.

The Board of Directors may provide a suitable seal, containing the name of the Corporation, which seal shall be in the charge of the Secretary of the Corporation. If and when so directed by the Board of Directors, duplicates of the seal may be kept and used by the Treasurer or by an Assistant Secretary, Assistant Treasurer or the Chief Financial Officer.

Section 8.2. Reliance upon Books, Reports, and Records.

Each director and each member of any committee designated by the Board of Directors of the Corporation shall, in the performance of his or her duties, be fully protected in relying in good faith upon the books and records of the Corporation and upon such information, opinions, reports or statements presented to the Corporation by any of its officers, agents or employees, or committees of the Board of Directors so designated, or by any other person or entity as to matters which such director or committee member reasonably believes are within such other person's or entity's professional or expert competence and that has been selected with reasonable care by or on behalf of the Corporation.

Section 8.3. Fiscal Year.

The fiscal year of the Corporation shall be as fixed by the Board of Directors.

Section 8.4. Time Periods.

In applying any provision of these bylaws that requires that an act be done or not be done a specified number of days before an event or that an act be done during a specified number of days before an event, calendar days shall be used, the day of the doing of the act shall be excluded, and the day of the event shall be included.

**SECTION 9 - AMENDMENTS**

These bylaws may be altered, amended or repealed in accordance with the Certificate of Incorporation and the DGCL.



COMMON STOCK  
NUMBER  
AT



COMMON STOCK  
SHARES

# Akebia Therapeutics, Inc.

CUSIP 00972D 10 5

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE

SEE REVERSE FOR CERTAIN DEFINITIONS

THIS CERTIFIES THAT

# SPECIMEN

Is the record holder of

FULLY PAID AND NON-ASSESSABLE SHARES OF THE COMMON STOCK, \$0.00010 PAR VALUE PER SHARE, OF  
**Akebia Therapeutics, Inc.**

transferable on the books of the Corporation in person or by duly authorized attorney upon surrender of this certificate properly endorsed.

This certificate is not valid unless countersigned by the Transfer Agent and registered by the Registrar.

Witness the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.

Dated:

PRESIDENT



SECRETARY

COUNTERSIGNED AND REGISTERED BY  
AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC  
TRANSFER AGENT AND REGISTRAR

AUTHORIZED SIGNATURE

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	- as tenants in common	UNIF GIFT MIN ACT	----- Custodian -----
TEN ENT	- as tenants by the entireties		(Cust) (Minor)
JT TEN	- as joint tenants with right of survivorship and not as tenants in common		under Uniform Gifts to Minors Act -----
			(State)

Additional abbreviations may also be used though not in the above list.

For value received, \_\_\_\_\_ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS INCLUDING POSTAL ZIP CODE OF ASSIGNEE

\_\_\_\_\_  
Shares of the common stock represented by the within Certificate, and do hereby irrevocably constitute and appoint \_\_\_\_\_

Attorney to transfer the said stock on the books of the within-named Corporation with full power of substitution in the premises.

Dated, \_\_\_\_\_

**NOTICE:** THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE, IN EVERY PARTICULAR WITHOUT ALTERATION OR ENLARGEMENT, OR ANY CHANGE WHATSOEVER.

**SIGNATURE(S) GUARANTEED:**

THE SIGNATURE(S) MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR (INSTITUTION BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 15c-15.



**FOURTH AMENDED AND RESTATED  
INVESTORS' RIGHTS AGREEMENT**

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Schedule A - Schedule of Investors

## **FOURTH AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT**

THIS FOURTH AMENDED AND RESTATED INVESTORS' RIGHTS AGREEMENT (this "Agreement") is made as of the [—] day of February, 2014 by and among AKEBIA THERAPEUTICS, INC., a Delaware corporation (the "Company"), each of the investors listed on Schedule A hereto, each of which is referred to in this Agreement as an "Investor" and collectively, the "Investors"), and any Additional Investor that becomes a party to this Agreement in accordance with Section 6.9 hereof.

### **RECITALS**

WHEREAS, certain of the Investors have previously purchased equity securities of the Company;

WHEREAS, the Company and certain Investors are parties to the "Series A Preferred Stock Purchase Agreements" dated as of January 23, 2008 and July 15, 2009;

WHEREAS, the Company and certain Investors are parties to the Series B Preferred Stock Purchase Agreement, dated as of April 6, 2011, by and among the Company and certain of the Investors (as it may be amended, restated, supplemented or otherwise modified from time to time, the "Series B Purchase Agreement");

WHEREAS, the Company and certain Investors are parties to the Series C Preferred Stock Purchase Agreement, dated as of May 10, 2013, by and among the Company and certain of the Investors (as it may be amended, restated, supplemented or otherwise modified from time to time, the "Series C Purchase Agreement");

WHEREAS, the Company, certain of the Investors and certain other Persons (as defined below) previously entered into an Investors' Rights Agreement, dated as of January 23, 2008 as Amended and Restated as of July 15, 2009, April 6, 2011 and May 10, 2013 (the "Prior Agreement");

WHEREAS, the Company and its existing Investors desire to amend and restate the Prior Agreement in its entirety on the terms set forth herein; and

WHEREAS, in accordance with Section 6.6 of the Prior Agreement, this Agreement has been executed by the Appropriate Percentage of the Registrable Securities then outstanding (as defined in the Prior Agreement);

NOW, THEREFORE, the parties hereby agree as follows:

1. Definitions. For purposes of this Agreement:

"Affiliate" means, with respect to any specified Person, any other Person who, directly or indirectly, controls, is controlled by, or is under common control with such Person, including without limitation any general partner, managing member, officer or director of such Person or any venture capital fund now or hereafter existing that is controlled by one or more

general partners or managing members of, or shares the same management company with, such Person, and provided that Satter Investment Management, LLC, Muneer A. Satter and all Persons for which Mr. Satter or any of his Immediate Family Members serves as trustee or investment advisor or any similar capacity (and their respective Affiliates) and any account held for the benefit of any such Person shall be Affiliates of one another, regardless of whether they would otherwise be deemed Affiliates hereunder.

“Appropriate Percentage” means fifty percent (50%).

“Common Stock” means shares of the Company’s common stock, par value \$0.00001 per share.

“Damages” means any loss, damage, or liability (joint or several) to which a party hereto may become subject under the Securities Act, the Exchange Act, or other federal or state law, insofar as such loss, damage, or liability (or any action in respect thereof) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in any registration statement of the Company, including any preliminary prospectus or final prospectus contained therein or any amendments or supplements thereto; (ii) an omission or alleged omission to state therein a material fact required to be stated therein, or necessary to make the statements therein not misleading; or (iii) any violation or alleged violation by the indemnifying party (or any of its agents or Affiliates) of the Securities Act, the Exchange Act, any state securities law, or any rule or regulation promulgated under the Securities Act, the Exchange Act, or any state securities law.

“Derivative Securities” means any securities or rights convertible into, or exercisable or exchangeable for (in each case, directly or indirectly), Common Stock, including options and warrants.

“Exchange Act” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Excluded Registration” means (i) a registration relating to the sale of securities to employees of the Company or a subsidiary pursuant to a stock option, stock purchase, or similar plan; (ii) a registration relating to an SEC Rule 145 transaction; (iii) a registration on any form that does not include substantially the same information as would be required to be included in a registration statement covering the sale of the Registrable Securities; or (iv) a registration in which the only Common Stock being registered is Common Stock issuable upon conversion of debt securities that are also being registered.

“Form S-1” means such form under the Securities Act as in effect on the date hereof or any successor registration form under the Securities Act subsequently adopted by the SEC.

“Form S-3” means such form under the Securities Act as in effect on the date hereof or any registration form under the Securities Act subsequently adopted by the SEC that permits incorporation of substantial information by reference to other documents filed by the Company with the SEC.

“GAAP” means generally accepted accounting principles in the United States.

“Holder” means any holder of Registrable Securities who is a party to this Agreement.

“Immediate Family Member” means a child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships, of a natural person referred to herein.

“Initiating Holders” means, collectively, Holders who properly initiate a registration request under this Agreement.

“Investor” means the persons named on Schedule A hereto, each person who hereafter becomes a signatory to this Agreement pursuant to Section 6.9 and any one of them, as the context may require; provided, however, that any such person shall cease to be considered an Investor for purposes of this Agreement at any time such person and his, her or its Affiliates collectively hold no shares of Preferred Stock.

“IPO” means the Company’s first underwritten public offering of its Common Stock under the Securities Act.

“Key Employee” means any executive-level employee (including division director and vice president-level positions) as well as any employee who, either alone or in concert with others, develops, invents, programs, or designs any Company Intellectual Property (as defined in the Series C Purchase Agreement).

“Major Investor” means any Investor that, individually or together with such Investor’s Affiliates, holds at least 27,500 shares of Registrable Securities (as adjusted for any stock split, stock dividend, combination, or other recapitalization or reclassification effected after the date hereof).

“New Securities” means, collectively, equity securities of the Company, whether or not currently authorized, as well as rights, options, or warrants to purchase such equity securities, or securities of any type whatsoever that are, or may become, convertible or exchangeable into or exercisable for such equity securities.

“P&G License Agreement” means that certain License Agreement dated as of September 4, 2007 between the Company and The Procter & Gamble Company.

“Person” means any individual, corporation, partnership, trust, limited liability company, association, foundation or other entity.

“Preferred Director” means any director of the Company that the holders of record of the Preferred Stock are entitled to elect pursuant to the Company’s Certificate of Incorporation.

“Preferred Stock” means shares of the Company’s Series A Preferred Stock, Series B Preferred Stock and Series C Preferred Stock.

“Prior Agreement” has the meaning set forth in the Recitals to this Agreement.

“Registrable Securities” means (i) the Common Stock issuable or issued upon conversion of the Preferred Stock; (ii) any Common Stock issued or issuable (directly or indirectly) upon conversion and/or exercise of any other securities of the Company, acquired by the Investors after the date hereof; and (iii) any Common Stock issued as (or issuable upon the conversion or exercise of any warrant, right, or other security that is issued as) a dividend or other distribution with respect to, or in exchange for or in replacement of, the shares referenced in clauses (i) and (ii) above; excluding in all cases, however, any Registrable Securities sold by a Person in a transaction in which the applicable rights under this Agreement are not assigned pursuant to Section 6.1, and excluding for purposes of Section 2 any shares for which registration rights have terminated pursuant to Section 2.13 of this Agreement. As to any particular Registrable Securities, such shares shall cease to be Registrable Securities when (i) a registration statement with respect to the sale of such securities shall have become effective under the Securities Act and such securities shall have been disposed of in accordance with such registration statement, (ii) all securities of the Company held by the Investor thereof (and all securities held by any other Persons with which such Investor must aggregate its sales under Rule 144) may be distributed without volume limitation or other restrictions on transfer under Rule 144 (including without application of paragraphs (c), (e), (f) and (h) of Rule 144), or (iii) such securities shall have ceased to be outstanding.

“Registrable Securities then outstanding” means the number of shares determined by adding the number of shares of outstanding Common Stock that are Registrable Securities and the number of shares of Common Stock issuable (directly or indirectly) pursuant to then exercisable and/or convertible securities that are Registrable Securities.

“Restricted Securities” means the securities of the Company required to bear the legend set forth in Section 2.12(b) hereof.

“SEC” means the Securities and Exchange Commission.

“SEC Rule 144” means Rule 144 promulgated by the SEC under the Securities Act.

“SEC Rule 145” means Rule 145 promulgated by the SEC under the Securities Act.

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Selling Expenses” means all underwriting discounts, selling commissions, and stock transfer taxes applicable to the sale of Registrable Securities, and fees and disbursements of counsel for any Holder, except for the fees and disbursements of the Selling Holder Counsel borne and paid by the Company as provided in Section 2.6.

“Series A Preferred Stock” means shares of the Company’s Series A Preferred Stock, par value \$0.00001 per share.

“Series B Preferred Stock” means shares of the Company’s Series B Preferred Stock, par value \$0.00001 per share.

“Series C Preferred Stock” means shares of the Company’s Series C Preferred Stock, par value \$0.00001 per share.

“Series C Purchase Agreement” has the meaning set forth in the Recitals to this Agreement.

2. Registration Rights. The Company covenants and agrees as follows:

2.1. Demand Registration.

(a) Form S-1 Demand. If at any time after the earlier of (i) five (5) years after the date of the Prior Agreement or (ii) one hundred eighty (180) days after the effective date of the registration statement for the IPO the Company receives a request from Holders of thirty percent (30%) of the Registrable Securities then outstanding that the Company file a Form S-1 registration statement with respect to Registrable Securities then outstanding, then the Company shall (i) within ten (10) days after the date such request is given, give notice thereof (the “Demand Notice”) to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within sixty (60) days after the date such request is given by the Initiating Holders, file a Form S-1 registration statement under the Securities Act covering all Registrable Securities that the Initiating Holders requested to be registered and any additional Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within ten (10) days of the date the Demand Notice is given, and in each case, subject to the limitations of Sections 2.1(c) and 2.3.

(b) Form S-3 Demand. If at any time when it is eligible to use a Form S-3 registration statement, the Company receives a request from Holders of at least thirty percent (30%) of the Registrable Securities then outstanding that the Company file a Form S-3 registration statement with respect to outstanding Registrable Securities of such Holders, then the Company shall (i) within ten (10) days after the date such request is given, give a Demand Notice to all Holders other than the Initiating Holders; and (ii) as soon as practicable, and in any event within forty-five (45) days after the date such request is given by the Initiating Holders, file a Form S-3 registration statement under the Securities Act covering all Registrable Securities requested to be included in such registration by any other Holders, as specified by notice given by each such Holder to the Company within ten (10) days of the date the Demand Notice is given, and in each case, subject to the limitations of Sections 2.1(c) and 2.3.

(c) Notwithstanding the foregoing obligations, if the Company furnishes to Holders requesting a registration pursuant to this Section 2.1 a certificate signed by the Company’s chief executive officer stating that in the good faith judgment of the Company’s Board of Directors it would be materially detrimental to the Company and its stockholders for such registration statement to either become effective or remain effective for as long as such



registration statement otherwise would be required to remain effective, because such action would (i) materially interfere with a significant acquisition, corporate reorganization, or other similar transaction involving the Company; (ii) require premature disclosure of material information that the Company has a bona fide business purpose for preserving as confidential; or (iii) render the Company unable to comply with requirements under the Securities Act or Exchange Act, then the Company shall have the right to defer taking action with respect to such filing, and any time periods with respect to filing or effectiveness thereof shall be tolled correspondingly, for a period of not more than sixty (60) days after the request of the Initiating Holders is given; provided, however, that the Company may not invoke this right more than once in any twelve (12) month period; and provided, further, that the Company shall not register any securities for its own account or that of any other stockholder during such sixty (60) day period other than an Excluded Registration.

(d) The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 2.1(a)(i) during the period that is sixty (60) days before the Company's good faith estimate of the date of filing of, and ending on a date that is one hundred eighty (180) days after the effective date of, a Company-initiated registration, provided, that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; (ii) after the Company has effected two registrations pursuant to Section 2.1(a); or (iii) if the Initiating Holders propose to dispose of shares of Registrable Securities that may be immediately registered on Form S-3 pursuant to a request made pursuant to Section 2.1(b). The Company shall not be obligated to effect, or to take any action to effect, any registration pursuant to Section 2.1(b)(i) during the period that is thirty (30) days before the Company's good faith estimate of the date of filing of, and ending on a date that is ninety (90) days after the effective date of, a Company-initiated registration, provided, that the Company is actively employing in good faith commercially reasonable efforts to cause such registration statement to become effective; or (ii) if the Company has effected three registrations pursuant to Section 2.1(b). A registration shall not be counted as "effected" for purposes of this Section 2.1(d) until such time as the applicable registration statement has been declared effective by the SEC, unless the Initiating Holders withdraw their request for such registration, elect not to pay the registration expenses therefor, and forfeit their right to one demand registration statement pursuant to Section 2.6, in which case such withdrawn registration statement shall be counted as "effected" for purposes of this Section 2.1(d).

2.2. Company Registration. If the Company proposes to register (including, for this purpose, a registration effected by the Company for stockholders other than the Holders) any of its Common Stock under the Securities Act in connection with the public offering of such securities solely for cash (other than in an Excluded Registration), the Company shall, at such time, promptly give each Holder notice of such registration. Upon the request of each Holder given within twenty (20) days after such notice is given by the Company, the Company shall, subject to the provisions of Section 2.3, cause to be registered all of the Registrable Securities that each such Holder has requested to be included in such registration. The Company shall have the right to terminate or withdraw any registration initiated by it under this Section 2.2 before the effective date of such registration, whether or not any Holder has elected to include Registrable Securities in such registration. The expenses (other than Selling Expenses) of such withdrawn registration shall be borne by the Company in accordance with Section 2.6.

### 2.3. Underwriting Requirements.

(a) If, pursuant to Section 2.1, the Initiating Holders intend to distribute the Registrable Securities covered by their request by means of an underwriting, they shall so advise the Company as a part of their request made pursuant to Section 2.1, and the Company shall include such information in the Demand Notice. The underwriter(s) will be selected by the Initiating Holders, subject only to the reasonable approval of the Company. In such event, the right of any Holder to include such Holder's Registrable Securities in such registration shall be conditioned upon such Holder's participation in such underwriting and the inclusion of such Holder's Registrable Securities in the underwriting to the extent provided herein. All Holders proposing to distribute their securities through such underwriting shall (together with the Company as provided in Section 2.4(e)) enter into an underwriting agreement in customary form with the underwriter(s) selected for such underwriting. Notwithstanding any other provision of this Section 2.3, if the managing underwriter(s) advise(s) the Initiating Holders in writing that marketing factors require a limitation on the number of shares to be underwritten, then the Initiating Holders shall so advise all Holders of Registrable Securities that otherwise would be underwritten pursuant hereto, and the number of Registrable Securities that may be included in the underwriting shall be allocated among such Holders of Registrable Securities, including the Initiating Holders, in proportion (as nearly as practicable) to the number of Registrable Securities owned by each Holder or in such other proportion as shall mutually be agreed to by all such selling Holders; provided, however, that the number of Registrable Securities held by the Holders to be included in such underwriting shall not be reduced unless all other securities are first entirely excluded from the underwriting. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares.

(b) In connection with any offering involving an underwriting of shares of the Company's capital stock pursuant to Section 2.2, the Company shall not be required to include any of the Holders' Registrable Securities in such underwriting unless the Holders accept the terms of the underwriting as agreed upon between the Company and its underwriters, and then only in such quantity as the underwriters in their sole discretion determine will not jeopardize the success of the offering by the Company. If the total number of securities, including Registrable Securities, requested by stockholders to be included in such offering exceeds the number of securities to be sold (other than by the Company) that the underwriters in their reasonable discretion determine is compatible with the success of the offering, then the Company shall be required to include in the offering only that number of such securities, including Registrable Securities, which the underwriters and the Company in their sole discretion determine will not jeopardize the success of the offering. If the underwriters determine that less than all of the Registrable Securities requested to be registered can be included in such offering, then the Registrable Securities that are included in such offering shall be allocated among the selling Holders in proportion (as nearly as practicable to) the number of Registrable Securities owned by each selling Holder or in such other proportions as shall mutually be agreed to by all such selling Holders. To facilitate the allocation of shares in accordance with the above provisions, the Company or the underwriters may round the number of shares allocated to any Holder to the nearest 100 shares. Notwithstanding the foregoing, in no event shall (i) the number of Registrable Securities included in the offering be reduced unless all other securities (other than securities to be sold by the Company) are first entirely excluded from the offering, or (ii) the

number of Registrable Securities included in the offering be reduced below thirty percent (30%) of the total number of securities included in such offering, unless such offering is the IPO, in which case the selling Holders may be excluded further if the underwriters make the determination described above and no other stockholder's securities are included in such offering. For purposes of the provision in this Section 2.3(b) concerning apportionment, for any selling Holder that is a partnership, limited liability company, or corporation, the partners, members, retired partners, retired members, stockholders, and Affiliates of such Holder, or the estates and Immediate Family Members of any such partners, retired partners, members, and retired members and any trusts for the benefit of any of the foregoing Persons, shall be deemed to be a single "selling Holder," and any pro rata reduction with respect to such "selling Holder" shall be based upon the aggregate number of Registrable Securities owned by all Persons included in such "selling Holder," as defined in this sentence.

(c) For purposes of Section 2.1, a registration shall not be counted as "effected" if, as a result of an exercise of the underwriter's cutback provisions in Section 2.3(a), fewer than fifty percent (50%) of the total number of Registrable Securities that Holders have requested to be included in such registration statement are actually included.

2.4. Obligations of the Company. Whenever required under this Section 2 to effect the registration of any Registrable Securities, the Company shall, as expeditiously as reasonably possible:

(a) prepare and file with the SEC a registration statement with respect to such Registrable Securities and use its commercially reasonable efforts to cause such registration statement to become effective and, upon the request of the Holders of a majority of the Registrable Securities registered thereunder, keep such registration statement effective for a period of up to one hundred twenty (120) days or, if earlier, until the distribution contemplated in the registration statement has been completed; provided, however, that (i) such one hundred twenty (120) day period shall be extended for a period of time equal to the period the Holder refrains, at the request of an underwriter of Common Stock (or other securities) of the Company, from selling any securities included in such registration, and (ii) in the case of any registration of Registrable Securities on Form S-3 that are intended to be offered on a continuous or delayed basis, subject to compliance with applicable SEC rules, such one hundred twenty (120) day period shall be extended for up to sixty (60) days, if necessary, to keep the registration statement effective until all such Registrable Securities are sold;

(b) prepare and file with the SEC such amendments and supplements to such registration statement, and the prospectus used in connection with such registration statement, as may be necessary to comply with the Securities Act in order to enable the disposition of all securities covered by such registration statement;

(c) furnish to the selling Holders such numbers of copies of a prospectus, including a preliminary prospectus, as required by the Securities Act, and such other documents as the Holders may reasonably request in order to facilitate their disposition of their Registrable Securities;

(d) use its commercially reasonable efforts to register and qualify the securities covered by such registration statement under such other securities or blue-sky laws of such jurisdictions as shall be reasonably requested by the selling Holders; provided, that the Company shall not be required to qualify to do business or to file a general consent to service of process in any such states or jurisdictions, unless the Company is already subject to service in such jurisdiction and except as may be required by the Securities Act;

(e) in the event of any underwritten public offering, enter into and perform its obligations under an underwriting agreement, in usual and customary form, with the underwriter(s) of such offering;

(f) use its commercially reasonable efforts to cause all such Registrable Securities covered by such registration statement to be listed on a national securities exchange or trading system and each securities exchange and trading system (if any) on which similar securities issued by the Company are then listed;

(g) provide a transfer agent and registrar for all Registrable Securities registered pursuant to this Agreement and provide a CUSIP number for all such Registrable Securities, in each case not later than the effective date of such registration;

(h) promptly make available for inspection by the selling Holders, any managing underwriter(s) participating in any disposition pursuant to such registration statement, and any attorney or accountant or other agent retained by any such underwriter or selected by the selling Holders, all financial and other records, pertinent corporate documents, and properties of the Company, and cause the Company's officers, directors, employees, and independent accountants to supply all information reasonably requested by any such seller, underwriter, attorney, accountant, or agent, in each case, as necessary or advisable to verify the accuracy of the information in such registration statement and to conduct appropriate due diligence in connection therewith;

(i) notify each selling Holder, promptly after the Company receives notice thereof, of the time when such registration statement has been declared effective or a supplement to any prospectus forming a part of such registration statement has been filed; and

(j) after such registration statement becomes effective, notify each selling Holder of any request by the SEC that the Company amend or supplement such registration statement or prospectus.

2.5. Furnish Information. It shall be a condition precedent to the obligations of the Company to take any action pursuant to this Section 2 with respect to the Registrable Securities of any selling Holder that such Holder shall furnish to the Company such information regarding itself, the Registrable Securities held by it, and the intended method of disposition of such securities as is reasonably required to effect the registration of such Holder's Registrable Securities.

2.6. Expenses of Registration. All expenses (other than Selling Expenses) incurred in connection with registrations, filings, or qualifications pursuant to Section 2, including all registration, filing, and qualification fees; printers' and accounting fees; fees and

disbursements of counsel for the Company; and the reasonable fees and disbursements, not to exceed \$75,000, of one counsel for the selling Holders (“Selling Holder Counsel”), shall be borne and paid by the Company; provided, however, that the Company shall not be required to pay for any expenses of any registration proceeding begun pursuant to Section 2.1 if the registration request is subsequently withdrawn at the request of the Holders of a majority of the Registrable Securities to be registered (in which case all selling Holders shall bear such expenses pro rata based upon the number of Registrable Securities that were to be included in the withdrawn registration), unless the Holders of a majority of the Registrable Securities agree to forfeit their right to one registration pursuant to Sections 2.1(a) or 2.1(b), as the case may be; provided, further, that if, at the time of such withdrawal, the Holders shall have learned of a material adverse change in the condition, business, or prospects of the Company from that known to the Holders at the time of their request and have withdrawn the request with reasonable promptness after learning of such information then the Holders shall not be required to pay any of such expenses and shall not forfeit their right to one registration pursuant to Sections 2.1(a) or 2.1(b). All Selling Expenses relating to Registrable Securities registered pursuant to this Section 2 shall be borne and paid by the Holders pro rata on the basis of the number of Registrable Securities registered on their behalf.

2.7. Delay of Registration. No Holder shall have any right to obtain or seek an injunction restraining or otherwise delaying any registration pursuant to this Agreement as the result of any controversy that might arise with respect to the interpretation or implementation of this Section 2.

2.8. Indemnification. If any Registrable Securities are included in a registration statement under this Section 2:

(a) To the extent permitted by law, the Company shall indemnify and hold harmless each selling Holder, and the partners, members, officers, directors, and stockholders of each such Holder; legal counsel and accountants for each such Holder; any underwriter (as defined in the Securities Act) for each such Holder; and each Person, if any, who controls such Holder or underwriter within the meaning of the Securities Act or the Exchange Act, against any Damages, and the Company will pay to each such Holder, underwriter, controlling Person, or other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Section 2.8(a) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Company, which consent shall not be unreasonably withheld, nor shall the Company be liable for any Damages to the extent that they arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of any such Holder, underwriter, controlling Person, or other aforementioned Person expressly for use in connection with such registration.

(b) To the extent permitted by law, each selling Holder, severally and not jointly, shall indemnify and hold harmless the Company, and each of its directors, each of its officers who has signed the registration statement, each Person (if any), who controls the Company within the meaning of the Securities Act, legal counsel and accountants for the

Company, any underwriter (as defined in the Securities Act), any other Holder selling securities in such registration statement, and any controlling Person of any such underwriter or other Holder, against any Damages, in each case only to the extent that such Damages arise out of or are based upon actions or omissions made in reliance upon and in conformity with written information furnished by or on behalf of such selling Holder expressly for use in connection with such registration; and each such selling Holder will pay to the Company and each other aforementioned Person any legal or other expenses reasonably incurred thereby in connection with investigating or defending any claim or proceeding from which Damages may result, as such expenses are incurred; provided, however, that the indemnity agreement contained in this Section 2.8(b) shall not apply to amounts paid in settlement of any such claim or proceeding if such settlement is effected without the consent of the Holder, which consent shall not be unreasonably withheld; and provided, further, that in no event shall the aggregate amounts payable by any Holder by way of indemnity or contribution under Sections 2.8(b) and 2.8(d) exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of fraud or willful misconduct by such Holder.

(c) Promptly after receipt by an indemnified party under this Section 2.8 of notice of the commencement of any action (including any governmental action) for which a party may be entitled to indemnification hereunder, such indemnified party will, if a claim in respect thereof is to be made against any indemnifying party under this Section 2.8, give the indemnifying party notice of the commencement thereof. The indemnifying party shall have the right to participate in such action and, to the extent the indemnifying party so desires, participate jointly with any other indemnifying party to which notice has been given, and to assume the defense thereof with counsel mutually satisfactory to the parties; provided, however, that an indemnified party (together with all other indemnified parties that may be represented without conflict by one counsel) shall have the right to retain one separate counsel, with the fees and expenses to be paid by the indemnifying party, if representation of such indemnified party by the counsel retained by the indemnifying party would be inappropriate due to actual or potential differing interests between such indemnified party and any other party represented by such counsel in such action.

(d) To provide for just and equitable contribution to joint liability under the Securities Act in any case in which either (i) any party otherwise entitled to indemnification hereunder makes a claim for indemnification pursuant to this Section 2.8 but it is judicially determined (by the entry of a final judgment or decree by a court of competent jurisdiction and the expiration of time to appeal or the denial of the last right of appeal) that such indemnification may not be enforced in such case, notwithstanding the fact that this Section 2.8 provides for indemnification in such case, or (ii) contribution under the Securities Act may be required on the part of any party hereto for which indemnification is provided under this Section 2.8, then, and in each such case, such parties will contribute to the aggregate losses, claims, damages, liabilities, or expenses to which they may be subject (after contribution from others) in such proportion as is appropriate to reflect the relative fault of each of the indemnifying party and the indemnified party in connection with the statements, omissions, or other actions that resulted in such loss, claim, damage, liability, or expense, as well as to reflect any other relevant equitable considerations. The relative fault of the indemnifying party and of the indemnified party shall be determined by reference to, among other things, whether the untrue or allegedly untrue statement of a material fact, or the omission or alleged omission of a material fact, relates

to information supplied by the indemnifying party or by the indemnified party and the parties' relative intent, knowledge, access to information, and opportunity to correct or prevent such statement or omission; provided, however, that, in any such case, (x) no Holder will be required to contribute any amount in excess of the public offering price of all such Registrable Securities offered and sold by such Holder pursuant to such registration statement, and (y) no Person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any Person who was not guilty of such fraudulent misrepresentation; and provided, further, that in no event shall a Holder's liability pursuant to this Section 2.8(d), when combined with the amounts paid or payable by such Holder pursuant to Section 2.8(b), exceed the proceeds from the offering received by such Holder (net of any Selling Expenses paid by such Holder), except in the case of willful misconduct or fraud by such Holder.

(e) Notwithstanding the foregoing, to the extent that the provisions on indemnification and contribution contained in the underwriting agreement entered into in connection with the underwritten public offering are in conflict with the foregoing provisions, the provisions in the underwriting agreement shall control.

(f) Unless otherwise superseded by an underwriting agreement entered into in connection with the underwritten public offering, the obligations of the Company and Holders under this Section 2.8 shall survive the completion of any offering of Registrable Securities in a registration under this Section 2, and otherwise shall survive the termination of this Agreement.

2.9. Reports Under Exchange Act. With a view to making available to the Holders the benefits of SEC Rule 144 and any other rule or regulation of the SEC that may at any time permit a Holder to sell securities of the Company to the public without registration or pursuant to a registration on Form S-3, the Company shall:

(a) make and keep available adequate current public information, as those terms are understood and defined in SEC Rule 144, at all times after the effective date of the registration statement filed by the Company for the IPO;

(b) use commercially reasonable efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act (at any time after the Company has become subject to such reporting requirements); and

(c) furnish to any Holder, so long as the Holder owns any Registrable Securities, forthwith upon request (i) to the extent accurate, a written statement by the Company that it has complied with the reporting requirements of SEC Rule 144 (at any time after ninety (90) days after the effective date of the registration statement filed by the Company for the IPO), the Securities Act, and the Exchange Act (at any time after the Company has become subject to such reporting requirements), or that it qualifies as a registrant whose securities may be resold pursuant to Form S-3 (at any time after the Company so qualifies); (ii) a copy of the most recent annual or quarterly report of the Company and such other reports and documents so filed by the Company; and (iii) such other information as may be reasonably requested in availing any

Holder of any rule or regulation of the SEC that permits the selling of any such securities without registration (at any time after the Company has become subject to the reporting requirements under the Exchange Act) or pursuant to Form S-3 (at any time after the Company so qualifies to use such form).

2.10. Limitations on Subsequent Registration Rights. From and after the date of this Agreement, the Company shall not, without the prior written consent of the Holders of more than the Appropriate Percentage of the Registrable Securities then outstanding, enter into any agreement with any holder or prospective holder of any securities of the Company that would allow such holder or prospective holder (i) to include such securities in any registration unless, under the terms of such agreement, such holder or prospective holder may include such securities in any such registration only to the extent that the inclusion of such securities will not reduce the number of the Registrable Securities of the Holders that are included or (ii) allow such holder or prospective holder to initiate a demand for registration of any securities held by such holder or prospective holder.

2.11. "Market Stand-off" Agreement. Each Holder hereby agrees that it will not, without the prior written consent of the managing underwriter, during the period commencing on the date of the final prospectus relating to the registration by the Company of shares of its Common Stock or any other equity securities under the Securities Act on a registration statement on Form S-1 or Form S-3, and ending on the date specified by the Company and the managing underwriter (such period not to exceed (x) one hundred eighty (180) days in the case of the IPO, or (y) if requested by the managing underwriter and approved by Holders of more than the Appropriate Percentage of the Registrable Securities, ninety (90) days in the case of any registration other than the IPO, (i) lend; offer; pledge; sell; contract to sell; sell any option or contract to purchase; purchase any option or contract to sell; grant any option, right, or warrant to purchase; or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock held immediately before the effective date of the registration statement for such offering or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash, or otherwise. Notwithstanding clause (i) and (ii) above, each Holder may distribute any or all of its shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock to any of its limited partners. Provided, however, that such limited partners who receive the distribution of any or all shares of Common Stock or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Common Stock shall still be subject to the other provisions of this Section 2.11. The foregoing provisions of this Section 2.11 shall not apply to the sale of any shares to an underwriter pursuant to an underwriting agreement, and shall be applicable to the Holders only if all officers and directors are subject to the same restrictions and the Company uses commercially reasonable efforts to obtain a similar agreement from all stockholders individually owning more than one percent (1%) of the Company's outstanding Common Stock (after giving effect to conversion into Common Stock of all outstanding Preferred Stock). The underwriters in connection with such registration are intended third-party beneficiaries of this Section 2.11 and shall have the right, power, and authority to enforce the provisions hereof as though they were a party hereto. Each Holder further agrees to execute such



agreements as may be reasonably requested by the underwriters in connection with such registration that are consistent with this Section 2.11 or that are necessary to give further effect thereto. Any discretionary waiver or termination of the restrictions of any or all of such agreements by the Company or the underwriters shall apply pro rata to all Holders subject to such agreements, based on the number of shares subject to such agreements.

2.12. Restrictions on Transfer.

(a) The Preferred Stock and the Registrable Securities shall not be sold, pledged, or otherwise transferred, and the Company shall not recognize and shall issue stop-transfer instructions to its transfer agent with respect to any such sale, pledge, or transfer, except upon the conditions specified in this Agreement, which conditions are intended to ensure compliance with the provisions of the Securities Act. A transferring Holder will cause any proposed purchaser, pledgee, or transferee of the Preferred Stock and the Registrable Securities held by such Holder to agree to take and hold such securities subject to the provisions and upon the conditions specified in this Agreement.

(b) Each certificate or instrument representing (i) the Preferred Stock, (ii) the Registrable Securities, and (iii) any other securities issued in respect of the securities referenced in clauses (i) and (ii), upon any stock split, stock dividend, recapitalization, merger, consolidation, or similar event, shall (unless otherwise permitted by the provisions of Section 2.12(c)) be stamped or otherwise imprinted with a legend substantially in the following form:

THE SHARES REPRESENTED HEREBY HAVE BEEN ACQUIRED FOR INVESTMENT AND HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933. SUCH SHARES MAY NOT BE SOLD, PLEDGED, OR TRANSFERRED IN THE ABSENCE OF SUCH REGISTRATION OR A VALID EXEMPTION FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SAID ACT.

THE SECURITIES REPRESENTED HEREBY MAY BE TRANSFERRED ONLY IN ACCORDANCE WITH THE TERMS OF AN AGREEMENT BETWEEN THE COMPANY AND THE STOCKHOLDER, A COPY OF WHICH IS ON FILE WITH THE SECRETARY OF THE COMPANY.

The Holders consent to the Company making a notation in its records and giving instructions to any transfer agent of the Restricted Securities in order to implement the restrictions on transfer set forth in this Section 2.12.

(c) The holder of each certificate representing Restricted Securities, by acceptance thereof, agrees to comply in all respects with the provisions of this Section 2. Before any proposed sale, pledge, or transfer of any Restricted Securities, unless there is in effect a registration statement under the Securities Act covering the proposed transaction, the Holder thereof shall give notice to the Company of such Holder's intention to effect such sale, pledge, or transfer. Each such notice shall describe the manner and circumstances of the proposed sale, pledge, or transfer in sufficient detail and, if reasonably requested by the Company, shall be accompanied at such Holder's expense by either (i) a written opinion of legal counsel who shall,

and whose legal opinion shall, be reasonably satisfactory to the Company, addressed to the Company, to the effect that the proposed transaction may be effected without registration under the Securities Act; (ii) a “no action” letter from the SEC to the effect that the proposed sale, pledge, or transfer of such Restricted Securities without registration will not result in a recommendation by the staff of the SEC that action be taken with respect thereto; or (iii) any other evidence reasonably satisfactory to counsel to the Company to the effect that the proposed sale, pledge, or transfer of the Restricted Securities may be effected without registration under the Securities Act, whereupon the Holder of such Restricted Securities shall be entitled to sell, pledge, or transfer such Restricted Securities in accordance with the terms of the notice given by the Holder to the Company. The Company will not require such a legal opinion or “no action” letter (x) in any transaction in compliance with SEC Rule 144 or (y) in any transaction in which such Holder distributes Restricted Securities to an Affiliate of such Holder for no consideration; provided, that each transferee agrees in writing to be subject to the terms of this Section 2.12. Each certificate or instrument evidencing the Restricted Securities transferred as above provided shall bear, except if such transfer is made pursuant to SEC Rule 144, the appropriate restrictive legend set forth in Section 2.12(b), except that such certificate shall not bear such restrictive legend if, in the opinion of counsel for such Holder and the Company, such legend is not required in order to establish compliance with any provisions of the Securities Act.

2.13. Termination of Registration Rights. The right of any Holder to request registration or inclusion of Registrable Securities in any registration pursuant to Section 2.1 or 2.2 shall terminate upon the closing of a Deemed Liquidation Event, as such term is defined in the Company’s Certificate of Incorporation.

### 3. Information and Observer Rights.

3.1. Delivery of Financial Statements. The Company shall deliver to each Major Investor:

(a) as soon as practicable, but in any event within ninety (90) days after the end of each fiscal year of the Company, (i) a balance sheet as of the end of such year, (ii) statements of income and of cash flows for such year, and a comparison between (x) the actual amounts as of and for such fiscal year and (y) the comparable amounts for the prior year and as included in the Budget (as defined in Section 3.1(e)) for such year, with an explanation of any material differences between such amounts and a schedule as to the sources and applications of funds for such year, and (iii) a statement of stockholders’ equity as of the end of such year, all such financial statements audited and certified by independent public accountants of nationally recognized standing selected by the Company;

(b) as soon as practicable, but in any event within thirty (30) days after the end of each of the first three (3) quarters of each fiscal year of the Company, unaudited statements of income and of cash flows for such fiscal quarter, and an unaudited balance sheet as of the end of such fiscal quarter, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(c) as soon as practicable, but in any event within thirty (30) days after the end of each month, a statement showing the number of shares of each class and series of capital stock and securities convertible into or exercisable for shares of capital stock outstanding at the end of the period, the Common Stock issuable upon conversion or exercise of any outstanding securities convertible or exercisable for Common Stock and the exchange ratio or exercise price applicable thereto, and the number of shares of issued stock options and stock options not yet issued but reserved for issuance, if any, all in sufficient detail as to permit the Major Investors to calculate their respective percentage equity ownership in the Company, and certified by the chief financial officer or chief executive officer of the Company as being true, complete, and correct;

(d) as soon as practicable, but in any event within thirty (30) days of the end of each month, an unaudited income statement and statement of cash flows for such month, and an unaudited balance sheet as of the end of such month, all prepared in accordance with GAAP (except that such financial statements may (i) be subject to normal year-end audit adjustments and (ii) not contain all notes thereto that may be required in accordance with GAAP);

(e) as soon as practicable, but in any event thirty (30) days before the end of each fiscal year, a budget and business plan for the next fiscal year (collectively, the “Budget”), prepared on a monthly basis, including balance sheets, income statements, and statements of cash flow for such months and, promptly after prepared, any other budgets or revised budgets prepared by the Company;

(f) with respect to the financial statements called for in Sections 3.1(a) and 3.1(b), a management discussion and analysis by the chief executive officer of the Company that includes updates and status of the Company’s material developments and activities; and

(g) such other information relating to the financial condition, business, prospects, or corporate affairs of the Company as any Major Investor may from time to time reasonably request; provided, however, that the Company shall not be obligated under this Section 3.1 to provide information (i) that the Company reasonably determines in good faith to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or (ii) the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

If, for any period, the Company has any subsidiary whose accounts are consolidated with those of the Company, then in respect of such period the financial statements delivered pursuant to the foregoing sections shall be the consolidated and consolidating financial statements of the Company and all such consolidated subsidiaries.

Notwithstanding anything else in this Section 3.1 to the contrary, the Company may cease providing the information set forth in this Section 3.1 during the period starting with the date thirty (30) days before the Company’s good-faith estimate of the date of filing of a registration statement if it reasonably concludes it must do so to comply with the SEC rules applicable to such registration statement and related offering; provided, that the Company’s covenants under this Section 3.1 shall be reinstated at such time as the Company is no longer actively employing its commercially reasonable efforts to cause such registration statement to become effective.

3.2. Inspection. The Company shall permit each Major Investor, at such Major Investor's expense, to visit and inspect the Company's properties; examine its books of account and records; and discuss the Company's affairs, finances, and accounts with its officers, during normal business hours of the Company as may be reasonably requested by the Major Investor; provided, however, that the Company shall not be obligated pursuant to this Section 3.2 to provide access to any information that it reasonably and in good faith considers to be a trade secret or confidential information (unless covered by an enforceable confidentiality agreement, in form acceptable to the Company) or the disclosure of which would adversely affect the attorney-client privilege between the Company and its counsel.

3.3. Observer Rights. As long as each of Venture Investors Early Stage Fund IV Limited Partnership, Athenian Venture Partners, AgeChem Venture Fund L.P., Cincinnati Cornerstone Investors AKB, LLC and Family Akebia Investments LLC (a) purchases shares of the Company's Series C Preferred Stock for at least \$1,499,000 in cash (excluding any conversion of Series X Preferred Stock) pursuant to the Series C Purchase Agreement and (b) continues to own not less than fifty percent (50%) of the aggregate number of shares of Preferred Stock that it purchased under the Series A Preferred Stock Purchase Agreements and the Series B Purchase Agreement and that it is purchasing (or acquiring as a result of the conversion of its shares of Series X Preferred Stock) under the Series C Purchase Agreement (or an equivalent number of shares of Common Stock issued upon conversion thereof), and as long as Triathlon Medical Ventures Fund, L.P. continues to own not less than fifty percent (50%) of the aggregate number of shares of Preferred Stock that it purchased under the Series A Preferred Stock Purchase Agreements and the Series B Purchase Agreement and that it is purchasing (or acquiring as a result of the conversion of its shares of Series X Preferred Stock) under the Series C Purchase Agreement (or an equivalent number of shares of Common Stock issued upon conversion thereof), the Company shall invite a representative of each such Person (provided that the representative of Triathlon Medical Ventures Fund, L.P. must be John M. Rice), as applicable, to attend all meetings of its Board of Directors in a nonvoting observer capacity and, in this respect, shall give such representative copies of all notices, minutes, consents, and other materials that it provides to its directors at the same time and in the same manner as provided to such directors; provided, however, that such representative shall agree to hold in confidence and trust and to act in a fiduciary manner with respect to all information so provided; and provided, further, that the Company reserves the right to withhold any information and to exclude such representative from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in disclosure of trade secrets or a conflict of interest, or if such Investor or its representative is a competitor of the Company.

3.4. Termination of Information and Observer Rights. The covenants set forth in Sections 3.1, 3.2, and 3.3 shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

3.5. Confidentiality. Each Investor agrees that such Investor will keep confidential and will not disclose, divulge, or use for any purpose (other than to monitor its investment in the Company) any confidential information obtained from the Company pursuant to the terms of this Agreement (including notice of the Company's intention to file a registration statement), unless such confidential information (a) is known or becomes known to the public in general (other than as a result of a breach of this Section 3.5 by such Investor), (b) is or has been independently developed or conceived by the Investor without use of the Company's confidential information, or (c) is or has been made known or disclosed to the Investor by a third party without a breach of any obligation of confidentiality such third party may have to the Company; provided, however, that an Investor may disclose confidential information (i) to its attorneys, accountants, consultants, and other professionals to the extent necessary to obtain their services in connection with monitoring its investment in the Company; (ii) to any prospective purchaser of any Registrable Securities from such Investor, if such prospective purchaser agrees to be bound by the provisions of this Section 3.5; (iii) to any existing or prospective Affiliate, partner, member, stockholder, or wholly owned subsidiary of such Investor in the ordinary course of business; provided, that such Investor informs such Person that such information is confidential and directs such Person to maintain the confidentiality of such information; or (iv) as may otherwise be required by law; provided, that the Investor promptly notifies the Company of such disclosure and takes reasonable steps to minimize the extent of any such required disclosure.

#### 4. Rights to Future Stock Issuances.

4.1. Right of First Offer. Subject to the terms and conditions of this Section 4.1 and applicable securities laws, if the Company proposes to offer or sell any New Securities, the Company shall first offer such New Securities to each Investor. An Investor shall be entitled to apportion the right of first offer hereby granted to it among itself and its Affiliates in such proportions as it deems appropriate.

(a) The Company shall give notice (the "Offer Notice") to each Investor, stating (i) its bona fide intention to offer such New Securities, (ii) the number of such New Securities to be offered, and (iii) the price and terms, if any, upon which it proposes to offer such New Securities.

(b) By notification to the Company within twenty (20) days after the Offer Notice is given, each Investor may elect to purchase or otherwise acquire, at the price and on the terms specified in the Offer Notice, up to that portion of such New Securities which equals the proportion that the Common Stock then held by such Investor (assuming full conversion and/or exercise, as applicable, of all Preferred Stock and other Derivative Securities then held by such Investor) bears to the total shares of Common Stock of the Company then outstanding (assuming full conversion and/or exercise, as applicable, of all Preferred Stock and other Derivative Securities). At the expiration of such twenty (20) day period, the Company shall promptly notify each Investor that elects to purchase or acquire all the shares available to it (each, a "Fully Exercising Investor") of any other Investor's failure to do likewise. During the ten (10) day period commencing after the Company has given such notice, each Fully Exercising Investor may, by giving notice to the Company, elect to purchase or acquire, in addition to the number of shares specified above, up to that portion of the New Securities for which Investors were entitled to subscribe but that were not subscribed for by the Investors which is equal to the

proportion that the Common Stock then held by such Fully Exercising Investor (assuming full conversion and/or exercise, as applicable, of all Preferred Stock and other Derivative Securities then held by such Fully Exercising Investor) bears to the Common Stock then held by all Fully Exercising Investors who wish to purchase such unsubscribed shares (assuming full conversion and/or exercise, as applicable, of all Preferred Stock and other Derivative Securities then held by all such Fully Exercising Investors). The closing of any sale pursuant to this Section 4.1(b) shall occur within the later of ninety (90) days of the date that the Offer Notice is given and the date of initial sale of New Securities pursuant to Section 4.1(c).

(c) If all New Securities referred to in the Offer Notice are not elected to be purchased or acquired as provided in Section 4.1(b), the Company may, during the ninety (90) day period following the expiration of the periods provided in Section 4.1(b), offer and sell the remaining unsubscribed portion of such New Securities to any Person or Persons at a price not less than, and upon terms no more favorable to the offeree than, those specified in the Offer Notice. If the Company does not enter into an agreement for the sale of the New Securities within such period, or if such agreement is not consummated within thirty (30) days of the execution thereof, the right provided hereunder shall be deemed to be revived and such New Securities shall not be offered unless first reoffered to the Investors in accordance with this Section 4.1.

(d) The right of first offer in this Section 4.1 shall not be applicable to (i) Exempted Securities (as defined in the Company's Certificate of Incorporation); and (ii) shares of Common Stock issued in the IPO.

(e) [Reserved]

(f) Notwithstanding any provision hereof to the contrary, in lieu of complying with the provisions of this Section 4.1, the Company may elect to give notice to the Investors within thirty (30) days after the issuance of New Securities. Such notice shall describe the type, price, and terms of the New Securities. Each Investor shall have twenty (20) days from the date notice is given to elect to purchase up to the number of New Securities that would, if purchased by such Investor, maintain such Investor's percentage-ownership position, calculated as set forth in Section 4.1(b) before giving effect to the issuance of such New Securities. The closing of such sale shall occur within sixty (60) days of the date notice is given to the Investors.

4.2. Termination. The covenants set forth in Section 4.1 shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, or (ii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

## 5. Additional Covenants.

5.1. Insurance. The Company shall use its commercially reasonable efforts to obtain, within ninety (90) days of the date hereof, from financially sound and reputable insurers Directors and Officers liability insurance and term "key-person" insurance on each of Joseph Gardner, Robert Shalwitz and William Daly, each in the amount of \$2,000,000 or such lesser amount determined by the Board of Directors (including a majority of the Preferred Directors)

and on terms and conditions satisfactory to the Board of Directors, and will use commercially reasonable efforts to cause such insurance policies to be maintained until such time as the Board of Directors determines that such insurance should be discontinued. The key-person policy shall name the Company as loss payee, and neither policy shall be cancelable by the Company without prior approval by the Board of Directors and holders of more than the Appropriate Percentage of the shares of Common Stock then issuable upon conversion of the then outstanding shares of Preferred Stock.

5.2. Employee Agreements. The Company will cause (i) each person now or hereafter employed by it or by any subsidiary (or engaged by the Company or any subsidiary as a consultant/independent contractor) with access to confidential information and/or trade secrets to enter into a nondisclosure and proprietary rights assignment agreement and (ii) each Key Employee to enter into a one (1) year noncompetition and nonsolicitation agreement, substantially in the form approved by the Board of Directors. In addition, the Company shall not amend, modify, terminate, waive, or otherwise alter, in whole or in part, any of the above-referenced agreements or any restricted stock agreement between the Company and any employee, without the consent of a majority of the Preferred Directors.

5.3. Qualified Small Business Stock. The Company shall use reasonable best efforts to cause the shares of Preferred Stock, as well as any shares into which such shares are converted, within the meaning of Section 1202(f) of the Internal Revenue Code (the "Code"), to constitute "qualified small business stock" as defined in Section 1202(c) of the Code; provided, however, that such requirement shall not be applicable if the Board of Directors of the Company determines, in its good-faith business judgment, that such qualification would unreasonably defer a sale or liquidation of the Company by virtue of the applicable "minimum holding period" requirements. The Company shall submit to its stockholders (including the Investors) and to the Internal Revenue Service any reports that may be required under Section 1202(d)(1)(C) of the Code and the regulations promulgated thereunder. In addition, within twenty (20) business days after any Investor's written request therefor, the Company shall, at its option, either (i) deliver to such Investor a written statement indicating whether (and what portion of) such Investor's interest in the Company constitutes "qualified small business stock" as defined in Section 1202(c) of the Code or (ii) deliver to such Investor such factual information in the Company's possession as is reasonably necessary to enable such Investor to determine whether (and what portion of) such Investor's interest in the Company constitutes "qualified small business stock" as defined in Section 1202(c) of the Code.

5.4. Matters Requiring Investor Approval. So long as at least twenty percent (20%) of the originally issued Series A Preferred Stock, at least twenty percent (20%) of the originally issued Series B Preferred Stock or at least twenty percent (20%) of the originally issued Series C Preferred Stock remains outstanding, the Company hereby covenants and agrees with each of the Investors that it shall not, without the approval of the Board of Directors, which approval must include the affirmative vote of a majority of the Preferred Directors then in office:

(a) make, or permit any subsidiary to make, any loan or advance in an aggregate amount in excess of \$100,000 to, or own any stock or other securities of, any subsidiary or other corporation, partnership, or other entity unless it is wholly owned by the Company;

(b) make, or permit any subsidiary to make, any loan or advance to any Person, including, without limitation, any employee or director of the Company or any subsidiary, except advances and similar expenditures in the ordinary course of business or under the terms of an employee stock or option plan approved by the Board of Directors;

(c) guarantee, directly or indirectly, or permit any subsidiary to guarantee, directly or indirectly, any indebtedness in an aggregate amount in excess of \$100,000, except for trade accounts of the Company or any subsidiary arising in the ordinary course of business;

(d) make any investment inconsistent with any investment policy approved by the Board of Directors;

(e) incur any aggregate indebtedness in excess of \$250,000, other than trade credit incurred in the ordinary course of business;

(f) otherwise enter into or be a party to any transaction with any director, officer, or employee of the Company or any "associate" (as defined in Rule 12b-2 promulgated under the Exchange Act) of any such Person, except for transactions contemplated by this Agreement, the Series A Purchase Agreements, the Series B Purchase Agreement, and the P&G License Agreement in effect as of the date of this Agreement;

(g) hire, terminate, or change the compensation of the executive officers, including approving any option grants or stock awards to executive officers;

(h) change the principal business of the Company, enter new lines of business, or exit the current line of business;

(i) sell, assign, license, pledge, or encumber material technology or intellectual property, other than licenses granted in the ordinary course of business;

(j) make any capital expenditure in excess of \$100,000; or

(k) adopt the Budget.

5.5. Board Matters. Unless otherwise determined by the vote of a majority of the directors then in office, the Board of Directors shall meet at least bi-monthly in accordance with an agreed-upon schedule. The Company shall reimburse the nonemployee directors for all reasonable out-of-pocket travel expenses incurred (consistent with the Company's travel policy) in connection with attending meetings of the Board of Directors. The Company shall cause to be established, as soon as practicable after such request, and will maintain, an audit and compensation committee, each of which shall consist solely of non-management directors. Each non-employee director shall be entitled in such person's discretion to be a member of any Board committee.

5.6. Successor Indemnification. If the Company or any of its successors or assignees consolidates with or merges into any other Person and is not the continuing or surviving corporation or entity of such consolidation or merger, then to the extent necessary,



proper provision shall be made so that the successors and assignees of the Company assume the obligations of the Company with respect to indemnification of members of the Board of Directors as in effect immediately before such transaction, whether such obligations are contained in the Company's Bylaws, its Certificate of Incorporation, or elsewhere, as the case may be.

5.7. Termination of Covenants. The covenants set forth in this Section 5, except for Section 5.6, shall terminate and be of no further force or effect (i) immediately before the consummation of the IPO, (ii) when the Company first becomes subject to the periodic reporting requirements of Section 12(g) or 15(d) of the Exchange Act, or (iii) upon a Deemed Liquidation Event, as such term is defined in the Company's Certificate of Incorporation, whichever event occurs first.

5.8. Limitation of Liability. The Company shall not enter into any agreement that could reasonably be expected to result in requiring such Investor in any series of the Company's Preferred Stock, without the written consent of such Investor, to participate in any transaction which would expose such Investor to liability (a) in excess of the proceeds actually received by such Investor under such transaction or (b) where the share of such liability of such Investor is higher than its pro rata portion of the proceeds actually received by such Investor under such transaction.

## 6. Miscellaneous.

6.1. Successors and Assigns. The rights under this Agreement may be assigned (but only with all related obligations) by a Holder to a transferee of Registrable Securities that (i) is an Affiliate of a Holder; (ii) is a Holder's Immediate Family Member or trust for the benefit of an individual Holder or one or more of such Holder's Immediate Family Members; or (iii) after such transfer, holds at least 1,000 shares of Registrable Securities (subject to appropriate adjustment for stock splits, stock dividends, combinations, and other recapitalizations after the date hereof); provided, however, that (x) the Company is, within a reasonable time after such transfer, furnished with written notice of the name and address of such transferee and the Registrable Securities with respect to which such rights are being transferred; and (y) such transferee agrees in a written instrument delivered to the Company to be bound by and subject to the terms and conditions of this Agreement, including the provisions of Section 2.11. For the purposes of determining the number of shares of Registrable Securities held by a transferee, the holdings of a transferee (1) that is an Affiliate or stockholder of a Holder; (2) who is a Holder's Immediate Family Member; or (3) that is a trust for the benefit of an individual Holder or such Holder's Immediate Family Member shall be aggregated together and with those of the transferring Holder; provided, further, that all transferees who would not qualify individually for assignment of rights shall have a single attorney-in-fact for the purpose of exercising any rights, receiving notices, or taking any action under this Agreement. The terms and conditions of this Agreement inure to the benefit of and are binding upon the respective successors and permitted assignees of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assignees any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided herein.

6.2. Governing Law. This Agreement shall be governed by, and construed in accordance with, the laws of the State of Delaware, regardless of the laws that might otherwise govern under applicable principles of conflicts of law.

6.3. Counterparts; Facsimile or PDF. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may also be executed and delivered by facsimile or PDF signature and in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

6.4. Titles and Subtitles. The titles and subtitles used in this Agreement are for convenience only and are not to be considered in construing or interpreting this Agreement.

6.5. Notices. All notices and other communications given or made pursuant to this Agreement shall be in writing and shall be deemed effectively given upon the earlier of actual receipt or: (i) personal delivery to the party to be notified; (ii) when sent, if sent by electronic mail or facsimile during the recipient's normal business hours, and if not sent during normal business hours, then on the recipient's next business day; (iii) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (iv) one (1) business day after the business day of deposit with a nationally recognized overnight courier, freight prepaid, specifying next-day delivery, with written verification of receipt. All communications shall be sent to the respective parties at their addresses as set forth on Schedule A hereto, or to the principal office of the Company and to the attention of the Chief Executive Officer, in the case of the Company, or to such email address, facsimile number, or address as subsequently modified by written notice given in accordance with this Section 6.5.

If notice is given to the Company, a copy shall also be sent to:

Thompson Hine LLP  
312 Walnut Street, 14th Floor  
Cincinnati, OH 45202-4089  
Attn: David J. Willbrand  
[david.willbrand@thompsonhine.com](mailto:david.willbrand@thompsonhine.com)

If notice is given to the Investors, a copy shall also be sent to:

Kirkland & Ellis LLP  
300 N. LaSalle St.  
Chicago, IL 60654  
Attn: Ted H. Zook, P.C.  
Roger D. Rhoten  
E-mail: [ted.zook@kirkland.com](mailto:ted.zook@kirkland.com)  
[roger.rhoten@kirkland.com](mailto:roger.rhoten@kirkland.com)

and

Edwards Wildman Palmer LLP  
Attn: Albert L. Sokol  
111 Huntington Avenue  
Boston, MA 02199 USA  
[asokol@edwardswildman.com](mailto:asokol@edwardswildman.com)

6.6. Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance, and either retroactively or prospectively) only with the written consent of the Company and the holders of more than the Appropriate Percentage of the Registrable Securities then outstanding; provided, that the Company may in its sole discretion waive compliance with Section 2.12(c) (and the Company's failure to object promptly in writing after notification of a proposed assignment allegedly in violation of Section 2.12(c) shall be deemed to be a waiver); and provided, further, that any provision hereof may be waived by any waiving party on such party's own behalf, without the consent of any other party. Notwithstanding the foregoing, this Agreement may not be amended or terminated and the observance of any term hereof may not be waived with respect to any Investor without the written consent of such Investor, unless such amendment, termination, or waiver applies to all Investors in the same fashion (it being agreed that a waiver of the provisions of Section 4 with respect to a particular transaction shall be deemed to apply to all Investors in the same fashion if such waiver does so by its terms, notwithstanding the fact that certain Investors may nonetheless, by agreement with the Company, purchase securities in such transaction). Notwithstanding the foregoing, the provisions of (a) Section 2.8(d), commencing with its words "provided, however", may not be amended or waived without the written consent of (i) the Company and (ii) the holders of ninety percent (90%) of the shares of Common Stock issuable upon conversion of the then outstanding shares of Preferred Stock and (iii) (A) Satter Investment Management, LLC so long as Satter Investment Management, LLC or any of its Affiliates holds any Preferred Stock or Common Stock issued upon conversion of any of such Preferred Stock, (B) Novartis Bioventures Ltd. so long as Novartis Bioventures Ltd. holds any Preferred Stock or Common Stock issued upon conversion of any of such Preferred Stock, and (C) Novo A/S so long as Novo A/S holds any Preferred Stock or Common Stock issued upon conversion of any of such Preferred Stock; (b) Section 3.3 may not be amended to terminate a designated right therein to appoint an observer to the Board of Directors without the written consent of the Company and at least fifty percent (50%) of the shares of Common Stock issuable upon conversion of the then outstanding shares of Preferred Stock held by the Persons entitled to appoint such observer; (c) Sections 4.1 and 4.2 may not be waived without the written consent of the holders of more than seventy percent (70%) of the shares of Common Stock issuable upon conversion of the then outstanding shares of Preferred Stock; and (d) Section 5.8, Section 6.6(a) and this Section 6.6(d) may not be amended or waived without the written consent of (i) the Company, (ii) the holders of ninety percent (90%) of the shares of Common Stock issuable upon conversion of the then outstanding shares of Preferred Stock and (iii) (A) Satter Investment Management, LLC so long as Satter Investment Management, LLC or any of its Affiliates holds any Preferred Stock or Common Stock issued upon conversion of any of such Preferred Stock, (B) Novartis Bioventures Ltd. so long as Novartis Bioventures Ltd. holds any Preferred Stock or Common Stock issued upon conversion of any of such Preferred Stock, and (C) Novo A/S so long as Novo A/S holds any Preferred Stock or Common Stock issued upon conversion of any of such Preferred Stock. The Company shall give prompt notice of any amendment or termination hereof or waiver hereunder to any

party hereto that did not consent in writing to such amendment, termination, or waiver. Any amendment, termination, or waiver effected in accordance with this Section 6.6 shall be binding on all parties hereto, regardless of whether any such party has consented thereto. No waivers of or exceptions to any term, condition, or provision of this Agreement, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, condition, or provision.

6.7. Severability. In case any one or more of the provisions contained in this Agreement is for any reason held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provision of this Agreement, and such invalid, illegal, or unenforceable provision shall be reformed and construed so that it will be valid, legal, and enforceable to the maximum extent permitted by law.

6.8. Aggregation of Stock. All shares of Registrable Securities held or acquired by Affiliates shall be aggregated together for the purpose of determining the availability of any rights under this Agreement and such Affiliated persons may apportion such rights as among themselves in any manner they deem appropriate.

6.9. Additional Investors. Notwithstanding anything to the contrary contained herein, if the Company issues additional shares of the Company's Preferred Stock after the date hereof, whether pursuant to the Series C Purchase Agreement or otherwise or if any Investor transfers any shares of the Company's Preferred Stock to any other Person, any purchaser or new holder of such shares of Preferred Stock may become a party to this Agreement by executing and delivering an additional counterpart signature page to this Agreement, and thereafter shall be deemed an "Investor" for all purposes hereunder. No action or consent by the Investors shall be required for such joinder to this Agreement by such additional Investor, so long as such additional Investor has agreed in writing to be bound by all of the obligations as an "Investor" hereunder.

6.10. Entire Agreement. This Agreement (including any Schedules and Exhibits hereto) amends and restates in its entirety the Prior Agreement, constitutes the full and entire understanding and agreement among the parties with respect to the subject matter hereof, and any other written or oral agreement relating to the subject matter hereof existing between the parties is expressly canceled.

6.11. [Reserved].

6.12. Delays or Omissions. No delay or omission to exercise any right, power, or remedy accruing to any party under this Agreement, upon any breach or default of any other party under this Agreement, shall impair any such right, power, or remedy of such nonbreaching or nondefaulting party, nor shall it be construed to be a waiver of or acquiescence to any such breach or default, or to any similar breach or default thereafter occurring, nor shall any waiver of any single breach or default be deemed a waiver of any other breach or default theretofore or thereafter occurring. All remedies, whether under this Agreement or by law or otherwise afforded to any party, shall be cumulative and not alternative.

6.13. Acknowledgment. The Company acknowledges that certain Investors are in the business of venture capital investing and therefore review the business plans and related proprietary information of many enterprises, including enterprises which may have products or services which compete directly or indirectly with those of the Company. Nothing in this Agreement shall preclude or in any way restrict the Investors from investing or participating in any particular enterprise whether or not such enterprise has products or services which compete with those of the Company.

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**SCHEDULE A**

**Investors**

## AKEBIA THERAPEUTICS, INC.

## INDEMNIFICATION AGREEMENT

This Indemnification Agreement (“**Agreement**”) is made as of [ ] by and between Akebia Therapeutics, Inc., a Delaware corporation (the “**Company**”), and [ ] (“**Indemnitee**”). This Agreement supersedes and replaces any and all previous Agreements between the Company and Indemnitee covering the subject matter of this Agreement.

**WHEREAS**, the Company and Indemnitee recognize the significant cost of directors’ and officers’ liability insurance and the general reductions in the coverage of such insurance;

**WHEREAS**, the Company and Indemnitee further recognize the substantial increase in corporate litigation in general, subjecting officers and directors to expensive litigation risks at the same time as the coverage of liability insurance has been severely limited;

**WHEREAS**, the Company desires to attract and retain the services of highly qualified individuals, such as Indemnitee, to serve as officers and directors of the Company and to indemnify its officers and directors so as to provide them with the maximum protection permitted by law;

**WHEREAS**, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, qualified individuals such as Indemnitee to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

**WHEREAS**, this Agreement is a supplement to and in furtherance of the Bylaws and Certificate of Incorporation of the Company and any resolutions adopted pursuant thereto, and shall not be deemed to substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder; and

**WHEREAS**, Indemnitee does not regard the protection available under the Bylaws and Certificate of Incorporation of the Company and insurance as adequate in the present circumstances, and may not be willing to serve as an officer or director without adequate protection, and the Company desires Indemnitee to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that he be so indemnified.

**NOW, THEREFORE**, in consideration for Indemnitee’s services as an officer or director of the Company, the Company and Indemnitee hereby agree as follows:

**1. Definitions.**

(a) A “**Change in Control**” shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

(i) *Acquisition of Stock by Third Party*. Any Person (as defined below) becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifteen percent (15%) or more of the combined voting power

of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding securities entitled to vote generally in the election of directors;

(ii) *Change in Board Composition.* During any period of two consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Company's board of directors, and any new directors (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 1(a)(i), 1(a)(iii) or 1(a)(iv)) whose election by the board of directors or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Company's board of directors;

(iii) *Corporate Transactions.* The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 50% of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity;

(iv) *Liquidation.* The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and

(v) *Other Events.* Any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or in response to any similar item on any similar schedule or form) promulgated under the Securities Exchange Act of 1934, as amended, whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 1(a), the following terms shall have the following meanings:

(1) "**Person**" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended; *provided, however,* that "**Person**" shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.



(2) “**Beneficial Owner**” shall have the meaning given to such term in Rule 13d-3 under the Securities Exchange Act of 1934, as amended; *provided, however*, that “**Beneficial Owner**” shall exclude any Person otherwise becoming a Beneficial Owner by reason of (i) the stockholders of the Company approving a merger of the Company with another entity or (ii) the Company’s board of directors approving a sale of securities by the Company to such Person.

(b) “**Corporate Status**” describes the status of a person who is or was a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise.

(c) “**DGCL**” means the General Corporation Law of the State of Delaware.

(d) “**Disinterested Director**” means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(e) “**Enterprise**” means the Company and any other corporation, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary.

(f) “**Expenses**” include all reasonable attorneys’ fees, retainers, court costs, transcript costs, fees and costs of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond or other appeal bond or their equivalent, and (ii) for purposes of Section 12(d), Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee’s rights under this Agreement or under any directors’ and officers’ liability insurance policies maintained by the Company. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee’s counsel as being reasonable shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) “**Independent Counsel**” means a law firm, or a partner or member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent (i) the Company or Indemnitee in any matter material to either such party (other than as Independent Counsel with respect to matters concerning Indemnitee under this Agreement, or other indemnitees under similar indemnification agreements), or (ii) any other

party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term “**Independent Counsel**” shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee’s rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(h) “**Proceeding**” means any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative or investigative (formal or informal) nature, including any appeal therefrom and including without limitation any such Proceeding pending as of the date of this Agreement, in which Indemnitee was, is or will be involved as a party, a potential party, a non-party witness or otherwise by reason of (i) the fact that Indemnitee is or was a director or officer of the Company, (ii) any action taken by Indemnitee or any action or inaction on Indemnitee’s part while acting as a director or officer of the Company, or (iii) the fact that he or she is or was serving at the request of the Company as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification or advancement of expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

(i) Reference to “**other enterprises**” shall include employee benefit plans; references to “**fin**es” shall include any excise taxes assessed on a person with respect to any employee benefit plan; references to “**serv**ing at the request of the Company” shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he or she reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “**not opposed to the best interests of the Company**” as referred to in this Agreement.

**2. Indemnity in Third-Party Proceedings.** The Company shall indemnify Indemnitee in accordance with the provisions of this Section 2 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 2, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his or her behalf in connection with such Proceeding or any

claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Company and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the Bylaws, vote of its stockholders or disinterested directors or applicable law.

**3. Indemnity in Proceedings by or in the Right of the Company.** The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses and, to the fullest extent permitted by law, amounts paid in settlement actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Company. No indemnification shall be made under this Section 3 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged by a court of competent jurisdiction to be liable to the Company, unless and only to the extent that the Delaware Court of Chancery or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification for such expenses as the Delaware Court of Chancery or such other court shall deem proper.

**4. Indemnification for Expenses of a Party Who is Wholly or Partly Successful.** Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to or a participant in and is successful (on the merits or otherwise) in defense of any Proceeding or any claim, issue or matter therein, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith. To the extent permitted by applicable law, if Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, in defense of one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf, to the fullest extent permitted by law, in connection with (a) each successfully resolved claim, issue or matter and (b) any claim, issue or matter related to any such successfully resolved claim, issuer or matter. For purposes of this section, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

**5. Indemnification for Expenses of a Witness.** Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his or her Corporate Status, a witness or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified to the extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith.

## 6. Additional Indemnification.

(a) Notwithstanding any limitation in Sections 2, 3 or 4, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his or her behalf in connection with the Proceeding or any claim, issue or matter therein.

(b) For purposes of Section 6(a), the meaning of the phrase “**to the fullest extent permitted by applicable law**” shall include, but not be limited to:

(i) the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL; and

(ii) the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

7. **Exclusions.** Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any Proceeding (or any part of any Proceeding):

(a) for which payment has actually been made to or on behalf of Indemnitee under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision;

(b) for an accounting or disgorgement of profits pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of federal, state or local statutory law or common law, if Indemnitee is held liable therefor (including pursuant to any settlement arrangements);

(c) for any reimbursement of the Company by Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by Indemnitee from the sale of securities of the Company, as required in each case under the Securities Exchange Act of 1934, as amended (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the “**Sarbanes-Oxley Act**”), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act), if Indemnitee is held liable therefor (including pursuant to any settlement arrangements);

(d) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees, agents or other indemnitees, unless (i) the Company's board of directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law, (iii) otherwise authorized in Section 12(d) or (iv) otherwise required by applicable law; or

(e) if prohibited by applicable law.

**8. Advances of Expenses.** The Company shall advance, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding), and such advancement shall be made as soon as reasonably practicable, but in any event no later than 30 days, after the receipt by the Company of a written statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding (which (a) shall include invoices received by Indemnitee in connection with such Expenses but, in the case of invoices in connection with legal services, any references to legal work performed or to expenditure made that would cause Indemnitee to waive any privilege accorded by applicable law shall not be included with the invoice, and (b) contain the affirmation required by Section 9(a)). Advances shall be unsecured and interest free and made without regard to Indemnitee's ability to repay such advances and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. Indemnitee hereby undertakes to repay any advance to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 8 shall not apply to the extent advancement is prohibited by law and shall not apply to any Proceeding for which indemnity is not permitted under this Agreement, but shall apply to any Proceeding referenced in Section 7(b) or 7(c) prior to a determination that Indemnitee is not entitled to be indemnified by the Company.

**9. Procedures for Notification and Defense of Claim.**

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses as soon as reasonably practicable following the receipt by Indemnitee of notice thereof. The written notification to the Company shall include, a description of the nature of the Proceeding and the facts underlying the Proceeding. The failure by Indemnitee to notify the Company will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights.

(b) If, at the time of the receipt of a notice of a Proceeding pursuant to the terms hereof, the Company has directors' and officers' liability insurance in effect, the Company shall give prompt notice of the commencement of the Proceeding to the insurers in accordance with the

procedures set forth in the applicable policies. The Company shall thereafter take all necessary and desirable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

#### **10. Procedures upon Application for Indemnification.**

(a) To obtain indemnification, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and as is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of the Proceeding. The Company shall, as soon as reasonably practicable after receipt of such a request for indemnification, advise the board of directors that Indemnitee has requested indemnification. Any delay in providing the request will not relieve the Company from its obligations under this Agreement.

(b) Upon written request by Indemnitee for indemnification pursuant to Section 10(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Company's board of directors, a copy of which shall be delivered to Indemnitee or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Company's board of directors, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Company's board of directors, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Company's board of directors, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Company's board of directors, by the stockholders of the Company. If it is determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten days after such determination. Indemnitee shall cooperate with the person, persons or entity making the determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information that is not privileged or otherwise protected from disclosure and that is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or expenses (including attorneys' fees and disbursements) reasonably incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(c) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 10(b), the Independent Counsel shall be selected as provided in this Section 10(c). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Company's board of directors, and the Company shall give written notice to Indemnitee advising him or her of the identity of the Independent Counsel so selected. If a

Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Company's board of directors, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; *provided, however*, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 1 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within 20 days after the later of (i) submission by Indemnitee of a written request for indemnification pursuant to Section 10(a) hereof and (ii) the final disposition of the Proceeding, the parties have not agreed upon an Independent Counsel, either the Company or Indemnitee may petition a court of competent jurisdiction for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and for the appointment as Independent Counsel of a person selected by the court or by such other person as the court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 10(b) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 12(a) of this Agreement, the Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(d) The Company agrees to pay the reasonable fees and expenses of any Independent Counsel and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

#### **11. Presumptions and Effect of Certain Proceedings.**

(a) In making a determination with respect to entitlement to indemnification hereunder, the person, persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 10(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by such person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 12(e), if the person, persons or entity empowered or selected under Section 10 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 11(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 10(b) of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within fifteen (15) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 10(b) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his or her conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith to the extent Indemnitee relied in good faith on (i) the records or books of account of the Enterprise, including financial statements, (ii) information supplied to Indemnitee by the directors or officers of the Enterprise in the course of their duties, (iii) the advice of legal counsel for the Enterprise or its board of directors or counsel selected by any committee of the board of directors or (iv) information or records given or reports made to the Enterprise by an independent certified public accountant, an appraiser, investment banker or other expert selected with reasonable care by the Enterprise or its board of directors or any committee of the board of directors. The provisions of this Section 11(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.



(e) Neither the knowledge, actions nor failure to act of any other director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

## 12. Remedies of Indemnitee.

(a) Subject to Section 12(e), in the event that (i) a determination is made pursuant to Section 10 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 8 or 12(d) of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 10 of this Agreement within 90 days after the later of the receipt by the Company of the request for indemnification or the final disposition of the Proceeding, (iv) payment of indemnification pursuant to this Agreement is not made (A) within ten days after a determination has been made that Indemnitee is entitled to indemnification or (B) with respect to indemnification pursuant to Sections 4, 5 and 12(d) of this Agreement, within 30 days after receipt by the Company of a written request therefor, or (v) the Company or any other person or entity takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or proceeding designed to deny, or to recover from, Indemnitee the benefits provided or intended to be provided to Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of Expenses. Indemnitee shall commence such proceeding seeking an adjudication within 180 days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 12(a); *provided, however*, that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce his or her rights under Section 4 of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication in accordance with this Agreement.

(b) Neither (i) the failure of the Company, its board of directors, any committee or subgroup of the board of directors, Independent Counsel or stockholders to have made a determination that indemnification of Indemnitee is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor (ii) an actual determination by the Company, its board of directors, any committee or subgroup of the board of directors, Independent Counsel or stockholders that Indemnitee has not met the applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has or has not met the applicable standard of conduct. In the event that a determination shall have been made pursuant to Section 10 of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this Section 12 shall be conducted in all respects as a *de novo* trial, on the merits, and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding commenced pursuant to this Section 12, the Company shall, to the fullest extent not prohibited by law, have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) To the fullest extent not prohibited by law, the Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 12 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement. If a determination shall have been made pursuant to Section 10 of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding commenced pursuant to this Section 12, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statements not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder.

(d) To the extent not prohibited by law, the Company shall indemnify Indemnitee against all Expenses that are incurred by Indemnitee in connection with any action for indemnification or advancement of Expenses from the Company under this Agreement unless as a part of such action, the court of competent jurisdiction determines that each of the material assertions made by Indemnitee as a basis for such action were not made in good faith or were frivolous or to the extent Indemnitee is successful in such action, and, if requested by Indemnitee, shall (as soon as reasonably practicable, but in any event no later than 30 days, after receipt by the Company of a written request therefor) advance such Expenses to Indemnitee, subject to the provisions of Section 8.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification shall be required to be made prior to the final disposition of the Proceeding.

13. **Contribution.** To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amounts incurred by Indemnitee, whether for Expenses, judgments, fines or amounts paid or to be paid in settlement, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the events and transactions giving rise to such Proceeding; and (ii) the relative fault of Indemnitee and the Company (and its other directors, officers, employees and agents) in connection with such events and transactions.

14. **Non-exclusivity.** The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Company's certificate of incorporation or bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. To the extent that a change in Delaware law, whether by statute or judicial decision,

permits greater indemnification or advancement of Expenses than would be afforded currently under the Company's certificate of incorporation and bylaws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. Except as expressly set forth herein, no right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. Except as expressly set forth herein, the assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

**15. Primary Responsibility.** The Company acknowledges that Indemnitee has or may have certain rights to indemnification and advancement of expenses provided by other entities and/or organizations (collectively, the "**Secondary Indemnitors**"). The Company hereby agrees (i) that it is the indemnitor of first resort (i.e., its obligations to Indemnitee are primary and any obligation of the Secondary Indemnitors to advance Expenses or to provide indemnification for the same Expenses or liabilities incurred by Indemnitee in connection with a Proceeding are secondary), (ii) that it shall be required to advance the full amount of Expenses incurred by Indemnitee and shall be liable for the full amount of all Expenses, judgments, penalties, fines and amounts paid in settlement to the extent legally permitted and as required by the terms of this Agreement and the certificate of incorporation or bylaws of the Company (or any other agreement between the Company and Indemnitee), without regard to any rights Indemnitee may have against the Secondary Indemnitors, and (iii) that, to the extent not in contravention of any insurance policy or policies providing liability or other insurance for the Company or any director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise, it irrevocably waives, relinquishes and releases the Secondary Indemnitors from any and all claims against the Secondary Indemnitors for contribution, subrogation or any other recovery of any kind in respect thereof. The Company further agrees that no advancement or payment by the Secondary Indemnitors on behalf of Indemnitee with respect to any claim for which indemnification is required under the terms of this Agreement shall affect the foregoing and the Secondary Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of Indemnitee against the Company. The Company and Indemnitee agree that the Secondary Indemnitors are express third party beneficiaries of the terms of this Section 15.

**16. No Duplication of Payments.** The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder (or for which advancement is provided hereunder) if and to the extent that Indemnitee has otherwise actually received payment for such amounts under any insurance policy, contract, agreement or otherwise.

**17. Insurance.** The Company shall, from time to time, make the good faith determination whether or not it is practicable for the Company to obtain and maintain a policy or policies of insurance with reputable insurance companies providing the officers and directors of the Company with coverage for losses from wrongful acts, or to ensure the Company's performance of its indemnification obligations under this Agreement. Among other considerations, the Company will weigh the costs of obtaining such insurance coverage against the protection afforded by such

coverage. In all policies of director and officer liability insurance, Indemnitee shall be named as an insured in such a manner as to provide Indemnitee the same rights and benefits as are accorded to the most favorably insured of the Company's directors, if Indemnitee is a director; or of the Company's officers, if Indemnitee is not a director of the Company but is an officer. Notwithstanding the foregoing, the Company shall have no obligation to obtain or maintain such insurance if the Company determines in good faith that such insurance is not reasonably available, if the premium costs for such insurance are disproportionate to the amount of coverage provided, if the coverage provided by such insurance is limited by exclusions so as to provide an insufficient benefit, or if Indemnitee is covered by similar insurance maintained by a subsidiary or parent of the Company.

18. **Subrogation.** In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

19. **Services to the Company.** Indemnitee agrees to serve as a director or officer of the Company or, at the request of the Company, as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of another Enterprise, for so long as Indemnitee is duly elected or appointed or until Indemnitee tenders his or her resignation or is removed from such position. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that any employment with the Company (or any of its subsidiaries or any Enterprise) is at will, and Indemnitee may be discharged at any time for any reason, with or without cause, with or without notice, except as may be otherwise expressly provided in any executed, written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Enterprise), any existing formal severance policies adopted by the Company's board of directors or, with respect to service as a director or officer of the Company, the Company's certificate of incorporation or bylaws or the DGCL. No such document shall be subject to any oral modification thereof. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve [as an [officer] [director] ], at the request of the Company, as a [director] [officer] [employee] [agent] [fiduciary] of [another corporation, partnership, joint venture, trust or other enterprise], as provided in Section 29 hereof.

20. **Successors.** This Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns, including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company, shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, executors, administrators and other legal representatives. The Company shall require and cause any successor (whether direct or indirect by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company, by written agreement, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place.

21. **Severability.** Nothing in this Agreement is intended to require or shall be construed as requiring the Company to do or fail to do any act in violation of applicable law. The Company's inability, pursuant to court order or other applicable law, to perform its obligations under this Agreement shall not constitute a breach of this Agreement. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (i) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (ii) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (iii) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

22. **Enforcement.** The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as a director or officer of the Company.

23. **Entire Agreement.** This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; *provided, however*, that this Agreement is a supplement to and in furtherance of the Company's certificate of incorporation and bylaws and applicable law.

24. **Modification and Waiver.** No supplement, modification or amendment to this Agreement shall be binding unless executed in writing by the parties hereto. No amendment, alteration or repeal of this Agreement shall adversely affect any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his or her Corporate Status prior to such amendment, alteration or repeal. No waiver of any of the provisions of this Agreement shall constitute or be deemed a waiver of any other provision of this Agreement nor shall any waiver constitute a continuing waiver.

25. **Notices.** All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, sent by facsimile or electronic mail or otherwise delivered by hand, messenger or courier service addressed:

(a) if to Indemnitee, to Indemnitee's address, facsimile number or electronic mail address as shown on the signature page of this Agreement or in the Company's records, as may be updated in accordance with the provisions hereof; or

(b) if to the Company, to the attention of the Chief Executive Officer or Chief Financial Officer of the Company at 245 First Street, Suite 1100, Cambridge, Massachusetts, 02142, or at such other current address as the Company shall have furnished to Indemnitee.

Each such notice or other communication shall for all purposes of this Agreement be treated as effective or having been given (i) if delivered by hand, messenger or courier service, when delivered (or if sent *via* a nationally-recognized overnight courier service, freight prepaid, specifying next-business-day delivery, one business day after deposit with the courier), or (ii) if sent *via* mail, at the earlier of its receipt or three days after the same has been deposited in a regularly-maintained receptacle for the deposit of the United States mail, addressed and mailed as aforesaid, or (iii) if sent *via* facsimile, upon confirmation of facsimile transfer or, if sent *via* electronic mail, upon confirmation of delivery when directed to the relevant electronic mail address, if sent during normal business hours of the recipient, or if not sent during normal business hours of the recipient, then on the recipient's next business day.

**26. Applicable Law and Consent to Jurisdiction.** This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court of Chancery, and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court of Chancery for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) appoint, to the extent such party is not otherwise subject to service of process in the State of Delaware, The Corporation Trust Company, Wilmington, New Castle County, Delaware as its agent in the State of Delaware as such party's agent for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court of Chancery, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court of Chancery has been brought in an improper or inconvenient forum.

**27. Counterparts.** This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. This Agreement may also be executed and delivered by facsimile signature and in counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

28. **Captions.** The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

29. **Duration of Agreement.** This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a director of the Company or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification hereunder or advancement of Expenses hereunder and of any Proceeding commenced by Indemnitee pursuant to Section 12 of this Agreement relating thereto. The indemnification and advancement of Expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, devisees, executors and administrators and other legal representatives.

*(signature page follows)*

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

**AKEBIA THERAPEUTICS, INC.**

\_\_\_\_\_  
*Signature of Authorized Signatory*

\_\_\_\_\_  
*Print Name*

\_\_\_\_\_  
*Title*

Address: 245 First Street, Suite 1100  
Cambridge, Massachusetts, 02142

**AGREED TO AND ACCEPTED:**

**INDEMNITEE:**

\_\_\_\_\_  
*Signature*

\_\_\_\_\_  
*Print Name*

\_\_\_\_\_  
*Director*

\_\_\_\_\_  
*Title*

Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_



<b>Name:</b>	[—]
<b>Number of Shares of Stock subject to Option:</b>	[—]
<b>Price Per Share:</b>	[\$—]
<b>Date of Grant:</b>	[—]

**STOCK OPTION AWARD**

**granted under the**

**AKEBIA THERAPEUTICS, INC.  
2014 INCENTIVE PLAN**

NON-STATUTORY STOCK OPTION AGREEMENT

This agreement (the “Agreement”) evidences a stock option granted by Akebia Therapeutics, Inc. (the “Company”) to the undersigned (the “Optionee”), pursuant to and subject to the terms of the Akebia Therapeutics, Inc. 2014 Incentive Plan (the “Plan”).

1. Grant of Stock Option. The Company grants to the Optionee on the date set forth above (the “Date of Grant”) an option (the “Stock Option”) to purchase, on the terms provided herein and in the Plan, the number of shares of Stock of the Company set forth above (the “Shares”) with an exercise price per Share as set forth above, in each case subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

The Stock Option evidenced by this Agreement is a non-statutory option (that is, an option that does not qualify as an incentive stock option under Section 422 of the Code) and is granted to the Optionee in connection with the Optionee’s employment by or service to the Company and its qualifying subsidiaries. For purposes of the immediately preceding sentence, “qualifying subsidiary” means a subsidiary of the Company as to which the Company has a “controlling interest” as described in Treas. Regs. §1.409A-1(b)(5)(iii)(E)(1).

2. Meaning of Certain Terms. Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan. The following terms have the following meanings:

- (a) “Beneficiary” means, in the event of the Optionee’s death, the beneficiary named in the written designation (in form acceptable to the Administrator) most recently filed with the Administrator by the Optionee prior to the Optionee’s death and not subsequently revoked, or, if there is no such designated beneficiary, the executor or administrator of the Optionee’s estate. An effective beneficiary designation will be treated as having been revoked only upon receipt by the Administrator, prior to the Optionee’s death, of an instrument of revocation in form acceptable to the Administrator.

- (b) “Change in Control” means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company’s securities: (i) any “person” (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the “beneficial owner” (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company’s then outstanding voting securities; (ii) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (iii) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (iv) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company’s assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the domicile of the Company’s incorporation; or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company’s securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.
- (c) “Incumbent Directors” means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).
- (d) “Option Holder” means the Optionee or, if as of the relevant time the Stock Option has passed to a Beneficiary, the Beneficiary.

3. Vesting; Method of Exercise; Treatment of the Stock Option Upon Cessation of Employment.

- (a) Vesting. As used herein with respect to the Stock Option or any portion thereof, the term “vest” means to become exercisable and the term

“vested” as applied to any outstanding Stock Option means that the Stock Option is then exercisable, subject in each case to the terms of the Plan. Unless earlier terminated, forfeited, relinquished or expired, and subject to the immediately following sentence, the Stock Option will vest in accordance with the terms of Schedule A attached hereto. Notwithstanding the foregoing, following the occurrence of a Change in Control, the Stock Option shall become fully vested and exercisable in the event that the Optionee is terminated without Cause or terminates his or her Employment in connection with a material diminishment of his or her job responsibilities or duties, or base compensation. Such vesting acceleration shall take place automatically and immediately on the date of such termination of Employment without Cause or in connection with such material diminishment in job responsibilities or duties, or base compensation, as the case may be, so that the Stock Option shall be fully vested and exercisable upon such termination.

- (b) Exercise of the Stock Option. No portion of the Stock Option may be exercised until such portion vests. Each election to exercise any vested portion of the Stock Option will be subject to the terms and conditions of the Plan and shall be in writing and signed by the Option Holder (or in such other form as is acceptable to the Administrator). Each such written exercise election must be received by the Company at its principal office or by such other party as the Administrator may prescribe and be accompanied by payment in full as provided in the Plan. The exercise price may be paid (i) by cash or check acceptable to the Administrator, (ii) at the election of the Optionee, by the Administrator’s holding back of Shares from this Stock Option having a fair market value equal to the exercise price in payment of the exercise price of this Stock Option, (iii) to the extent permitted by the Administrator, through a broker assisted cashless exercise program acceptable to the Administrator<sup>1</sup>, (iv) by such other means, if any, as may be acceptable to the Administrator or (v) by any combination of the foregoing permissible forms of payment. In the event that the Stock Option is exercised by a person other than the Optionee, the Company will be under no obligation to deliver Shares hereunder unless and until it is satisfied as to the authority of the Option Holder to exercise the Stock Option and compliance with applicable securities laws. The latest date on which the Stock Option or any portion thereof may be exercised will be the 10th anniversary of the Date of Grant (the “Final Exercise Date”); provided, however, if at such time the Optionee is prohibited by applicable law or written Company policy applicable to similarly situated employees from engaging in any open-market sales of Stock, the Final Exercise Date will be automatically

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<sup>1</sup> Note to Draft – a cashless exercise by a Section 16 officer will be treated as sale of securities, so it will need to be reported on Form 4 and the “sold” shares are subject to matching under Section 16.

extended to thirty (30) days following the date the Optionee is no longer prohibited from engaging in such open-market sales. If the Stock Option is not exercised by the Final Exercise Date the Stock Option or any remaining portion thereof will thereupon immediately terminate.

- (c) Treatment of the Stock Option Upon Cessation of Employment. If the Optionee's Employment ceases, the Stock Option, to the extent not already vested, will be immediately forfeited, and any vested portion of the Stock Option that is then outstanding will be treated as follows:

(i) Subject to clauses (ii) and (iii) below and Section 4 of this Agreement, the Stock Option to the extent vested immediately prior to the cessation of the Optionee's Employment will remain exercisable until the earlier of (A) the date that is three (3) months following the date of such cessation of Employment, or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c)(i) will thereupon immediately terminate.

(ii) Subject to clause (iii) below and Section 4 of this Agreement, the Stock Option, to the extent vested prior to the cessation of the Optionee's Employment due to death, will remain exercisable until the earlier of (A) the first anniversary of the Optionee's death or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c)(ii) will thereupon immediately terminate.

(iii) If the Optionee's Employment is terminated by the Company and its subsidiaries in connection with an act or failure to act constituting Cause (as the Administrator, in its sole discretion, may determine), or such termination occurs in circumstances that in the determination of the Administrator would have entitled the Company and its subsidiaries to terminate the Optionee's Employment for Cause, this Stock Option (whether or not vested) will immediately terminate and be forfeited upon such termination.

#### 4. Forfeiture; Recovery of Compensation.

- (a) The Administrator may cancel, rescind, withhold or otherwise limit or restrict the Stock Option at any time if the Optionee is not in compliance with all applicable provisions of this Agreement and the Plan, or if the Optionee breaches any agreement with the Company or its subsidiaries with respect to non-competition, non-solicitation, invention assignment or confidentiality, including, but not limited to, any employment agreement or offer letter with the Company or the Employee Agreement (Confidentiality, Non-Solicitation, Non-Competition and Developments Agreement) attached hereto as Schedule B.

- (b) By accepting the Stock Option, the Optionee expressly acknowledges and agrees that his or her rights, and those of any permitted transferee of the Stock Option, under the Stock Option, including to any Stock acquired under the Stock Option or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). Nothing in the preceding sentence shall be construed as limiting the general application of Section 8 of this Agreement.

5. Transfer of Stock Option. The Stock Option may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6. Withholding. The exercise of the Stock Option will give rise to “wages” subject to withholding. The Optionee expressly acknowledges and agrees that the Optionee’s rights hereunder, including the right to be issued Shares upon exercise, are subject to the Optionee promptly paying to the Company in cash (or by such other means as may be acceptable to the Administrator in its discretion) all taxes required to be withheld. No Shares will be transferred pursuant to the exercise of this Stock Option unless and until the person exercising this Stock Option has remitted to the Company an amount sufficient to satisfy any federal, state, or local withholding tax requirements, or has made other arrangements satisfactory to the Company with respect to such taxes. The Optionee authorizes the Company and its subsidiaries to withhold such amount from any amounts otherwise owed to the Optionee, but nothing in this sentence shall be construed as relieving the Optionee of any liability for satisfying his or her obligation under the preceding provisions of this Section.

7. Effect on Employment. Neither the grant of the Stock Option, nor the issuance of Shares upon exercise of the Stock Option, will give the Optionee any right to be retained in the employ or service of the Company or any of its Affiliates, affect the right of the Company or any of its Affiliates to discharge or discipline such Optionee at any time, or affect any right of such Optionee to terminate his or her Employment at any time.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been furnished to the Optionee. By exercising all or any part of the Stock Option, the Optionee agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan shall control.

9. Acknowledgements. The Optionee acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same instrument, (ii) this agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, shall constitute an original signature

for all purposes hereunder and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Optionee.

*[Signature page follows.]*

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer.

AKEBIA THERAPEUTICS, INC.

By: \_\_\_\_\_  
Name: [—]  
Title: [—]

Dated:

Acknowledged and Agreed:

By \_\_\_\_\_  
[Optionee's Name]

*[Signature Page to Non-Statutory Time-Based Option Agreement]*

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**Schedule A**  
**Time Vesting Schedule**

The Stock Option, unless earlier terminated or forfeited, will vest, subject to Optionee's continuous Employment through the applicable vesting date, (i) as to 25% of the total number of Shares subject to the Stock Option on the first anniversary of the Date of Grant; and (ii) as to the remaining 75% of Shares subject to the Stock Option, ratably on the first day of each calendar quarter between the one-year anniversary of the date of grant and the fourth anniversary of the Date of Grant.



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**Schedule B**  
**Employee Agreement**

**Name:** [—]  
**Number of Shares of Stock subject to Option:** [—]  
**Exercise Price Per Share:** \$[—]  
**Date of Grant:** [—]

**OFFICER STOCK OPTION AWARD**

**granted under the**

**AKEBIA THERAPEUTICS, INC.  
2014 INCENTIVE PLAN**

NON-STATUTORY STOCK OPTION AGREEMENT

This agreement (the "Agreement") evidences a stock option granted by Akebia Therapeutics, Inc. (the "Company") to the undersigned (the "Optionee"), pursuant to and subject to the terms of the Akebia Therapeutics, Inc. 2014 Incentive Plan (the "Plan").

1. Grant of Stock Option. The Company grants to the Optionee on the date set forth above (the "Date of Grant") an option (the "Stock Option") to purchase, on the terms provided herein and in the Plan, the number of shares of Stock of the Company set forth above (the "Shares") with an exercise price per Share as set forth above, in each case subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

The Stock Option evidenced by this Agreement is a non-statutory option (that is, an option that does not qualify as an incentive stock option under Section 422 of the Code) and is granted to the Optionee in connection with the Optionee's employment by or service to the Company and its qualifying subsidiaries. For purposes of the immediately preceding sentence, "qualifying subsidiary" means a subsidiary of the Company as to which the Company has a "controlling interest" as described in Treas. Regs. §1.409A-1(b)(5)(iii)(E)(1).

2. Meaning of Certain Terms. Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan. The following terms have the following meanings:

- (a) "Beneficiary" means, in the event of the Optionee's death, the beneficiary named in the written designation (in form acceptable to the Administrator) most recently filed with the Administrator by the Optionee prior to the Optionee's death and not subsequently revoked, or, if there is no such designated beneficiary, the executor or administrator of the Optionee's estate. An effective beneficiary designation will be treated as having been revoked only upon receipt by the Administrator, prior to the Optionee's death, of an instrument of revocation in form acceptable to the Administrator.

- (b) “Change in Control” means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company’s securities: (i) any “person” (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the “beneficial owner” (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company’s then outstanding voting securities; (ii) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (iii) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (iv) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company’s assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the domicile of the Company’s incorporation; or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company’s securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.
- (c) “Incumbent Directors” means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).
- (d) “Option Holder” means the Optionee or, if as of the relevant time the Stock Option has passed to a Beneficiary, the Beneficiary.
3. Vesting; Method of Exercise; Treatment of the Stock Option Upon Cessation of Employment and a Change in Control.
- (a) Vesting. As used herein with respect to the Stock Option or any portion thereof, the term “vest” means to become exercisable and the term

“vested” as applied to any outstanding Stock Option means that the Stock Option is then exercisable, subject in each case to the terms of the Plan. Unless earlier terminated, forfeited, relinquished or expired, and subject to the immediately following sentence, the Stock Option will vest in accordance with the terms of Schedule A attached hereto. Notwithstanding the foregoing, if, in connection with a Change in Control, the Stock Option is not assumed or continued, and nor is a new award granted in substitution thereof by the acquiror or survivor (or an affiliate of the acquiror or survivor) in accordance with the provisions of Section 7 of the Plan, the Stock Option, to the extent outstanding immediately prior to such Change in Control but not then vested in full, shall automatically become fully vested and exercisable upon such Change in Control.

- (b) Exercise of the Stock Option. No portion of the Stock Option may be exercised until such portion vests. Each election to exercise any vested portion of the Stock Option will be subject to the terms and conditions of the Plan and shall be in writing and signed by the Option Holder (or in such other form as is acceptable to the Administrator). Each such written exercise election must be received by the Company at its principal office or by such other party as the Administrator may prescribe and be accompanied by payment in full as provided in the Plan. The exercise price may be paid (i) by cash or check acceptable to the Administrator, (ii) at the election of the Optionee, by the Administrator’s holding back of Shares from this Stock Option having a fair market value equal to the exercise price in payment of the exercise price of this Stock Option, (iii) to the extent permitted by the Administrator, through a broker assisted cashless exercise program acceptable to the Administrator<sup>1</sup>, (iv) by such other means, if any, as may be acceptable to the Administrator or (v) by any combination of the foregoing permissible forms of payment. In the event that the Stock Option is exercised by a person other than the Optionee, the Company will be under no obligation to deliver Shares hereunder unless and until it is satisfied as to the authority of the Option Holder to exercise the Stock Option and compliance with applicable securities laws. The latest date on which the Stock Option or any portion thereof may be exercised will be the 10th anniversary of the Date of Grant (the “Final Exercise Date”); provided, however, if at such time the Optionee is prohibited by applicable law or written Company policy applicable to similarly situated employees from engaging in any open-market sales of Stock, the Final Exercise Date will be automatically extended to thirty (30) days following the date the Optionee is no longer prohibited from engaging in such open-market sales. If the Stock Option is not exercised by the Final Exercise Date the Stock Option or any remaining portion thereof will thereupon immediately terminate.

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<sup>1</sup> Note to Draft – a cashless exercise by a Section 16 officer will be treated as sale of securities, so it will need to be reported on Form 4 and the “sold” shares are subject to matching under Section 16.

- (c) Treatment of the Stock Option Upon Cessation of Employment. If the Optionee's Employment ceases, the Stock Option, to the extent not already vested, will be immediately forfeited, and any vested portion of the Stock Option that is then outstanding will be treated as follows:
- (i) Subject to clauses (ii) and (iii) below and Section 4 of this Agreement, the Stock Option to the extent vested immediately prior to the cessation of the Optionee's Employment will remain exercisable until the earlier of (A) the date that is three (3) months following the date of such cessation of Employment, or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c)(i) will thereupon immediately terminate.
  - (ii) Subject to clause (iii) below and Section 4 of this Agreement, the Stock Option, to the extent vested prior to the cessation of the Optionee's Employment due to death, will remain exercisable until the earlier of (A) the first anniversary of the Optionee's death or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c)(ii) will thereupon immediately terminate.
  - (iii) If the Optionee's Employment is terminated by the Company and its subsidiaries in connection with an act or failure to act constituting Cause (as the Administrator, in its sole discretion, may determine), or such termination occurs in circumstances that in the determination of the Administrator would have entitled the Company and its subsidiaries to terminate the Optionee's Employment for Cause, this Stock Option (whether or not vested) will immediately terminate and be forfeited upon such termination.

4. Forfeiture; Recovery of Compensation.

- (a) The Administrator may cancel, rescind, withhold or otherwise limit or restrict the Stock Option at any time if the Optionee is not in compliance with all applicable provisions of this Agreement and the Plan, or if the Optionee breaches any agreement with the Company or its subsidiaries with respect to non-competition, non-solicitation, invention assignment or confidentiality, including, but not limited to, any employment agreement or offer letter with the Company or the Employee Agreement (Confidentiality, Non-Solicitation, Non-Competition and Developments Agreement) attached hereto as Schedule B.

(b) By accepting the Stock Option, the Optionee expressly acknowledges and agrees that his or her rights, and those of any permitted transferee of the Stock Option, under the Stock Option, including to any Stock acquired under the Stock Option or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). Nothing in the preceding sentence shall be construed as limiting the general application of Section 8 of this Agreement.

5. Transfer of Stock Option. The Stock Option may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6. Withholding. The exercise of the Stock Option will give rise to “wages” subject to withholding. The Optionee expressly acknowledges and agrees that the Optionee’s rights hereunder, including the right to be issued Shares upon exercise, are subject to the Optionee promptly paying to the Company in cash (or by such other means as may be acceptable to the Administrator in its discretion) all taxes required to be withheld. No Shares will be transferred pursuant to the exercise of this Stock Option unless and until the person exercising this Stock Option has remitted to the Company an amount sufficient to satisfy any federal, state, or local withholding tax requirements, or has made other arrangements satisfactory to the Company with respect to such taxes. The Optionee authorizes the Company and its subsidiaries to withhold such amount from any amounts otherwise owed to the Optionee, but nothing in this sentence shall be construed as relieving the Optionee of any liability for satisfying his or her obligation under the preceding provisions of this Section.

7. Effect on Employment. Neither the grant of the Stock Option, nor the issuance of Shares upon exercise of the Stock Option, will give the Optionee any right to be retained in the employ or service of the Company or any of its Affiliates, affect the right of the Company or any of its Affiliates to discharge or discipline such Optionee at any time, or affect any right of such Optionee to terminate his or her Employment at any time.

8. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been furnished to the Optionee. By exercising all or any part of the Stock Option, the Optionee agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan shall control.

9. Acknowledgements. The Optionee acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same instrument, (ii) this agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, shall constitute an original signature for all purposes hereunder and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Optionee.

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*[Signature page follows.]*

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer.

AKEBIA THERAPEUTICS, INC.

By: \_\_\_\_\_  
Name: [—]  
Title: [—]

Dated:

Acknowledged and Agreed:

By \_\_\_\_\_  
[Optionee's Name]

*[Signature Page to Non-Statutory Time-Based Option Agreement - Officers]*



**Schedule A**  
**Time Vesting Schedule**

The Stock Option, unless earlier terminated or forfeited, will vest, subject to Optionee's continuous Employment through the applicable vesting date, (i) as to 25% of the total number of Shares subject to the Stock Option on the first anniversary of the Date of Grant; and (ii) as to the remaining 75% of Shares subject to the Stock Option, ratably on the first day of each calendar quarter between the one-year anniversary of the date of grant and the fourth anniversary of the Date of Grant.

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**Schedule B**  
**Employee Agreement**

**Name:** [—]  
**Number of Shares of Stock subject to Option:** [—]  
**Exercise Price Per Share:** \$[—]  
**Date of Grant:** [—]

**NON-EMPLOYEE DIRECTOR STOCK OPTION AWARD**

**granted under the**

**AKEBIA THERAPEUTICS, INC.  
2014 INCENTIVE PLAN**

NON-STATUTORY STOCK OPTION AGREEMENT

This agreement (the "Agreement") evidences a stock option granted by Akebia Therapeutics, Inc. (the "Company") to the undersigned (the "Optionee"), pursuant to and subject to the terms of the Akebia Therapeutics, Inc. 2014 Incentive Plan (the "Plan").

1. Grant of Stock Option. The Company grants to the Optionee on the date set forth above (the "Date of Grant") an option (the "Stock Option") to purchase, on the terms provided herein and in the Plan, the number of shares of Stock of the Company set forth above (the "Shares") with an exercise price per Share as set forth above, in each case subject to adjustment pursuant to Section 7 of the Plan in respect of transactions occurring after the date hereof.

The Stock Option evidenced by this Agreement is a non-statutory option (that is, an option that does not qualify as an incentive stock option under Section 422 of the Code) and is granted to the Optionee in connection with the Optionee's employment by or service to the Company and its qualifying subsidiaries. For purposes of the immediately preceding sentence, "qualifying subsidiary" means a subsidiary of the Company as to which the Company has a "controlling interest" as described in Treas. Regs. §1.409A-1(b)(5)(iii)(E)(1).

2. Meaning of Certain Terms. Except as otherwise defined herein, all capitalized terms used herein have the same meaning as in the Plan. The following terms have the following meanings:

- (a) "Beneficiary" means, in the event of the Optionee's death, the beneficiary named in the written designation (in form acceptable to the Administrator) most recently filed with the Administrator by the Optionee prior to the Optionee's death and not subsequently revoked, or, if there is no such designated beneficiary, the executor or administrator of the Optionee's estate. An effective beneficiary designation will be treated as having been revoked only upon receipt by the Administrator, prior to the Optionee's death, of an instrument of revocation in form acceptable to the Administrator.

- (b) “Change in Control” means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company’s securities: (i) any “person” (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the “beneficial owner” (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company’s then outstanding voting securities; (ii) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (iii) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (iv) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company’s assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (i) its sole purpose is to change the domicile of the Company’s incorporation; or (ii) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company’s securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.
- (c) “Incumbent Directors” means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).
- (d) “Option Holder” means the Optionee or, if as of the relevant time the Stock Option has passed to a Beneficiary, the Beneficiary.
3. Vesting; Method of Exercise; Treatment of the Stock Option Upon Cessation of Employment and a Change in Control.
- (a) Vesting. As used herein with respect to the Stock Option or any portion thereof, the term “vest” means to become exercisable and the term

“vested” as applied to any outstanding Stock Option means that the Stock Option is then exercisable, subject in each case to the terms of the Plan. Unless earlier terminated, forfeited, relinquished or expired, and subject to the immediately following sentence, the Stock Option will vest in accordance with the terms of Schedule A attached hereto. Notwithstanding the foregoing, if, in connection with a Change in Control, the Stock Option is not assumed or continued, and nor is a new award granted in substitution thereof by the acquiror or survivor (or an affiliate of the acquiror or survivor) in accordance with the provisions of Section 7 of the Plan, the Stock Option, to the extent outstanding immediately prior to such Change in Control but not then vested in full, shall automatically become fully vested and exercisable upon such Change in Control.

- (b) Exercise of the Stock Option. No portion of the Stock Option may be exercised until such portion vests. Each election to exercise any vested portion of the Stock Option will be subject to the terms and conditions of the Plan and shall be in writing and signed by the Option Holder (or in such other form as is acceptable to the Administrator). Each such written exercise election must be received by the Company at its principal office or by such other party as the Administrator may prescribe and be accompanied by payment in full as provided in the Plan. The exercise price may be paid (i) by cash or check acceptable to the Administrator, (ii) at the election of the Optionee, by the Administrator’s holding back of Shares from this Stock Option having a fair market value equal to the exercise price in payment of the exercise price of this Stock Option, (iii) to the extent permitted by the Administrator, through a broker assisted cashless exercise program acceptable to the Administrator, (iv) by such other means, if any, as may be acceptable to the Administrator or (v) by any combination of the foregoing permissible forms of payment. In the event that the Stock Option is exercised by a person other than the Optionee, the Company will be under no obligation to deliver Shares hereunder unless and until it is satisfied as to the authority of the Option Holder to exercise the Stock Option and compliance with applicable securities laws. The latest date on which the Stock Option or any portion thereof may be exercised will be the 10th anniversary of the Date of Grant (the “Final Exercise Date”); provided, however, if at such time the Optionee is prohibited by applicable law or written Company policy applicable to similarly situated employees, directors or other service providers from engaging in any open-market sales of Stock, the Final Exercise Date will be automatically extended to thirty (30) days following the date the Optionee is no longer prohibited from engaging in such open-market sales. If the Stock Option is not exercised by the Final Exercise Date the Stock Option or any remaining portion thereof will thereupon immediately terminate.

- (c) Treatment of the Stock Option Upon Cessation of Employment. If the Optionee's Employment ceases, the Stock Option, to the extent not already vested, will be immediately forfeited, and any vested portion of the Stock Option that is then outstanding will be treated as follows:
- (i) Subject to clauses (ii) and (iii) below and Section 4 of this Agreement, the Stock Option to the extent vested immediately prior to the cessation of the Optionee's Employment will remain exercisable until the earlier of (A) the date that is three (3) months following the date of such cessation of Employment, or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c)(i) will thereupon immediately terminate.
  - (ii) Subject to clause (iii) below and Section 4 of this Agreement, the Stock Option, to the extent vested prior to the cessation of the Optionee's Employment due to death, will remain exercisable until the earlier of (A) the first anniversary of the Optionee's death or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c)(ii) will thereupon immediately terminate.
  - (iii) If the Optionee's Employment is terminated by the Company and its subsidiaries in connection with an act or failure to act constituting Cause (as the Administrator, in its sole discretion, may determine), or such termination occurs in circumstances that in the determination of the Administrator would have entitled the Company and its subsidiaries to terminate the Optionee's Employment for Cause, this Stock Option (whether or not vested) will immediately terminate and be forfeited upon such termination.
4. Forfeiture; Recovery of Compensation.
- (a) The Administrator may cancel, rescind, withhold or otherwise limit or restrict the Stock Option at any time if the Optionee is not in compliance with all applicable provisions of this Agreement and the Plan, or if the Optionee breaches any agreement with the Company or its subsidiaries with respect to non-competition, non-solicitation, invention assignment or confidentiality.
  - (b) By accepting the Stock Option, the Optionee expressly acknowledges and agrees that his or her rights, and those of any permitted transferee of the Stock Option, under the Stock Option, including to any Stock acquired under the Stock Option or proceeds from the disposition thereof, are subject to Section 6(a)(5) of the Plan (including any successor provision). Nothing in the preceding sentence shall be construed as limiting the general application of Section 7 of this Agreement.

5. Transfer of Stock Option. The Stock Option may not be transferred except as expressly permitted under Section 6(a)(3) of the Plan.

6. Effect on Service Relationship. Neither the grant of the Stock Option, nor the issuance of Shares upon exercise of the Stock Option, will give the Optionee any right to be retained in the employ or service of the Company or any of its Affiliates, affect the right of the Company or any of its Affiliates to discharge or discipline such Optionee at any time, or affect any right of such Optionee to terminate his or her Employment at any time.

7. Provisions of the Plan. This Agreement is subject in its entirety to the provisions of the Plan, which are incorporated herein by reference. A copy of the Plan as in effect on the Date of Grant has been furnished to the Optionee. By exercising all or any part of the Stock Option, the Optionee agrees to be bound by the terms of the Plan and this Agreement. In the event of any conflict between the terms of this Agreement and the Plan, the terms of the Plan shall control.

8. Acknowledgements. The Optionee acknowledges and agrees that (i) this Agreement may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same instrument, (ii) this agreement may be executed and exchanged using facsimile, portable document format (PDF) or electronic signature, which, in each case, shall constitute an original signature for all purposes hereunder and (iii) such signature by the Company will be binding against the Company and will create a legally binding agreement when this Agreement is countersigned by the Optionee.

*[Signature page follows.]*

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized officer.

AKEBIA THERAPEUTICS, INC.

By: \_\_\_\_\_  
Name: [—]  
Title: [—]

Dated:

Acknowledged and Agreed:

By \_\_\_\_\_  
[Optionee's Name]

*[Signature Page to Non-Statutory Time-Based Option Agreement – Non-Employee Directors]*



**Schedule A**  
**Time Vesting Schedule**

*Option 1: Initial Grant Vesting Provision:*

[The Stock Option, unless earlier terminated or forfeited, will vest, subject to Optionee's continuous Employment through the applicable vesting date, (i) as to 25% of the total number of Shares subject to the Stock Option on the first anniversary of the Date of Grant; and (ii) as to the remaining 75% of Shares subject to the Stock Option, ratably on the first day of each calendar quarter between the one-year anniversary of the date of grant and the fourth anniversary of the Date of Grant.]

*Option 2: Subsequent Annual Grant Vesting Provision:*

[The Stock Option, unless earlier terminated or forfeited, will vest, subject to Optionee's continuous Employment through the applicable vesting date, as to 100% of the total number of Shares subject to the Stock Option on the earlier of: (i) the first anniversary of the Date of Grant or (ii) immediately prior to the date on which the first annual meeting of shareholders of the Company is held after the Date of Grant.]

## AKEBIA THERAPEUTICS, INC.

## NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Non-employee members of the board of directors (the “**Board**”) of Akebia Therapeutics, Inc. (the “**Company**”) shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Program (this “**Program**”), which is being adopted pursuant to the Board’s resolutions on February 28, 2014. The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a “**Non-Employee Director**”) who may be eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program shall be reviewed by the Board periodically and may be amended, modified or terminated by the Board at any time in its sole discretion and nothing herein should be construed as a guarantee to any Non-Employee Director of any particular level of cash or equity compensation. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. This Program shall become effective on the date of the closing of the initial public offering of Company common stock (the “**Effective Date**”).

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall be eligible to receive an annual retainer of \$35,000 for service on the Board.

(b) Additional Annual Retainers. In addition to the annual retainer payable pursuant to Section 1(a) above, a Non-Employee Director shall be eligible to receive the following annual retainers:

(i) Chairman of the Board. A Non-Employee Director serving as Chairman of the Board shall be eligible to receive an additional annual retainer of \$20,000 for such service; provided, that, in the event that a Non-Employee Director is one of two concurrently serving Chairmen of the Board, the additional annual retainer payable to such Non-Employee Director pursuant to this Section 1(b)(i) shall be \$10,000.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee shall be eligible to receive an additional annual retainer of \$15,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shall be eligible to receive an additional annual retainer of \$7,500 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee shall be eligible to receive an additional annual retainer of \$10,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall be eligible to receive an additional annual retainer of \$5,000 for such service.

(vi) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall be eligible to receive an additional annual retainer of \$7,500 for such service. A Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall be eligible to receive an additional annual retainer of \$3,750 for such service.

(c) Payment of Retainers. The annual retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. Each award described below shall be granted under and shall be subject to the terms and provisions of the Company's 2014 Incentive Plan or any other successor Company equity incentive plan under which awards are permitted to be made to non-employee directors (the "**Equity Plan**") and shall be granted subject to the execution and delivery of a non-qualified stock option award agreement, including attached exhibits, in substantially the form previously approved by the Board or the Compensation Committee. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options will be granted in accordance with the terms and conditions of, and hereby are subject in all respects to, the Equity Plan. For the avoidance of doubt, if there is any conflict between the terms of the Equity Plan and this Program, the Plan shall control.

(a) Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall be eligible to receive, on the date of such initial election or appointment, an option to purchase 10,000 shares of the Company's common stock (subject to adjustment as provided in the Equity Plan). The awards described in this Section 2(a) shall be referred to as "**Initial Awards**." No Non-Employee Director shall be granted more than one Initial Award.

(b) Subsequent Awards. A Non-Employee Director who (i) has been serving on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted, on the date of such annual meeting, an option to purchase 5,000 shares of the Company's common stock (subject to adjustment as provided in the Equity Plan). The awards described in this Section 2(b) shall be referred to as "**Subsequent Awards**." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Award on the date of such meeting as well.

(c) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section 2(b) above.

(d) Terms of Awards Granted to Non-Employee Directors.

(i) Purchase Price. The per share exercise price of each option granted to a Non-Employee Director shall equal the fair market value (as determined pursuant to the Equity Plan) of a share of common stock on the date the option is granted.

(ii) Vesting. Each Initial Award shall vest and become exercisable in accordance with the following schedule, subject to the Non-Employee Director remaining in continuous service on the Board through each such vesting date: 25% of the Initial Award shall vest on the one-year anniversary of the date of grant and 75% shall vest ratably on the first day of each calendar quarter between the one-year anniversary of the date of grant and the fourth anniversary of the date of grant. Each Subsequent Award shall vest and become exercisable in full on the earlier of (A) the first anniversary of the date of grant or (B) immediately prior to the next annual meeting of the Company's stockholders after the date of grant, subject to the Non-Employee Director remaining in continuous service on the Board through such vesting date. In no event shall any portion of an Initial Award or Subsequent Award that is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board become vested and exercisable thereafter.

(iii) Term. The term of each stock option granted to a Non-Employee Director shall be ten (10) years from the date the option is granted.

3. Reimbursements. The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of his or her duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures, as in effect from time to time. To the extent that any reimbursement under the this Program provides for a deferral of compensation under Section 409A of the Internal Revenue Code of 1986, as amended: (a) the amount eligible for reimbursement in one calendar year may not affect the amount eligible for reimbursement in any other calendar year; (b) the right to reimbursement is not subject to liquidation or exchange for another benefit; and (c) any such reimbursement of an expense must be made on or before the last day of the calendar year following the calendar year in which the expense was incurred.

\* \* \* \* \*

**EXECUTIVE SEVERANCE AGREEMENT**

This EXECUTIVE SEVERANCE AGREEMENT (the “*Agreement*”) is entered into as of the     day of                     , 2014 (the “*Effective Date*”), by and between **Akebia Therapeutics, Inc.**, a Delaware corporation (“*Akebia*” or the “*Company*”), and [FULL LEGAL NAME], a resident of the [State] [Commonwealth] of (the “*Executive*”).

**WHEREAS**, Executive is a valued employee of the Company; and

**WHEREAS**, the Company desires to provide certain severance benefits to Executive according to, and contingent upon, the terms and conditions stated herein (the “*Severance Benefits*”).

**NOW, THEREFORE**, in consideration of the foregoing and the mutual promises contained herein, and of other good and valuable consideration, including the compensation to be received by Executive from the Company from time to time, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

**1. Definitions.**

(a) Cause. For purposes of this Agreement, and in each case as determined by the Compensation Committee of the Company’s Board of Directors (the “*Compensation Committee*”) in its sole and reasonable discretion, the following will constitute “*Cause*”:

- (i) indictment or conviction for either any felony offense or any other crime involving dishonesty;
- (ii) participation in any fraud, theft, embezzlement or other misconduct or act of dishonesty involving the Company or any of its subsidiaries;
- (iii) intentional damage to any property of the Company or any of its subsidiaries;
- (iv) breach of the holder’s duties of good faith and fair dealing that are owed to the Company or any of its subsidiaries;
- (v) breach or violation of any agreement between Executive and the Company or any of its subsidiaries, including, without limitation, any employment, confidentiality, non-competition, non-solicitation or assignment of inventions agreement;
- (vi) conduct which in the good faith and reasonable determination of the Board of Directors demonstrates gross unfitness to serve;
- (vii) failure to comply with the code of conduct of the Company or any of its subsidiaries or any other policies of the Company that have been approved by the Board of Directors or its authorized delegate,
- (viii) insubordination or failure to follow the directions of the Board of Directors or of the Chief Executive Officer or President of the Company; or
- (ix) any other conduct by Executive that could be expected to be harmful to the business, interests or reputation of the Company or any of its subsidiaries.

Executive shall have thirty (30) days after notice from the Company to cure the deficiency leading to the Cause determination (except with respect to Sections 1(a)(i) and 1(a)(ii) above, for which no notice is required) if, in the sole and reasonable discretion of the Compensation Committee, such deficiency is curable.

(b) **Good Reason.** For purposes of this Agreement the following will constitute “**Good Reason**” for Executive to terminate his/her employment with the Company. For the avoidance of doubt, Executive shall not be considered to have terminated his/her employment for Good Reason unless Executive has (A) reasonably determined in good faith that a Good Reason condition has occurred; (B) not consented to the occurrence that s/he alleges constitutes Good Reason; (C) given the Company written Notice of Termination for Good Reason not more than sixty (60) days after the initial existence of the alleged condition giving rise to Good Reason; (D) given the Company at least thirty (30) days after receipt of such notice to cure the alleged deficiency; and (E) terminated his/her employment within sixty (60) days following the Company’s receipt of such notice.

(i) a material reduction in the nature or status of Executive’s responsibilities, authority, position or duties (unless arising directly or indirectly in connection with a documented and significant performance issue in Executive’s then-current position, as determined by the Compensation Committee in its sole and reasonable discretion). Notwithstanding the foregoing, neither of the following shall constitute Good Reason: (A) a reassignment of Executive to a position within the Company of substantially equivalent level or status with respect to Executive’s responsibilities and duties existing immediately prior to such reassignment, or (B) a change in reporting structure;

(ii) a material adverse reduction in the amount of aggregate cash compensation provided to Executive or failure by the Company to pay such compensation, except where such reduction occurs contemporaneously with the implementation of a firm-wide cost-reduction program affecting comparable executives (a “**Reduction Program**”);

(iii) the failure by the Company to continue in effect any incentive compensation plan in which Executive participates, unless an equitable alternative compensation arrangement has been provided, except that to the extent that participation in such plans has been reduced or eliminated for all other eligible executives, in which case the failure to continue Executive in any such plan shall not constitute Good Reason; or

(iv) establishment of the Company’s primary operations in any place beyond a fifty (50) mile radius of Cambridge, Massachusetts; provided, that Executive primarily provides services in Cambridge at the time of such establishment.

In all respects, the definition of Good Reason shall be interpreted to comply with Code Section 409A, and any successor statute, regulation and guidance thereto.

(c) **Change in Control.** For purposes of this Agreement, a “**Change in Control**” means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company’s securities:

(i) any “person” (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the “beneficial owner” (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company’s then outstanding voting securities;

(ii) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors. "Incumbent Directors" will mean directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company);

(iii) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or

(iv) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets.

Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (a) its sole purpose is to change the domicile of the Company's incorporation; or (b) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

In all respects, the definition of Change in Control shall be interpreted to comply with Code Section 409A, and any successor statute, regulation and guidance thereto.

(d) **Notice of Termination.** For purposes of this Agreement, a "**Notice of Termination**" means a notice which, if applicable, sets forth the specific "cause" or "good reason" provision of this Section 2 and sets forth the effective date of termination.

(e) **Disability.** For purposes of this Agreement, "**Disability**" means Executive's inability by reason of physical or mental impairment to perform his/her job duties for a period exceeding twelve (12) consecutive weeks.

**2. Termination of Agreement.** This Agreement will terminate automatically upon (a) Executive's termination for Cause; (b) mutual agreement between the Company and Executive; (c) Executive's death, or (d) Executive's Disability. Upon termination of this Agreement, Executive or his/her heirs or estate (as applicable) only will be entitled to payments required by law or agreement and benefits afforded under the Company's employee benefit plans existing at the time of termination and in which the Executive participates.

**3. Severance Benefits Upon Termination of Executive's Employment.** If Executive's employment is terminated, then s/he may be entitled to certain monetary and non-monetary compensation and benefits as set forth below (the "**Severance Benefits**"):

(a) **Termination by the Company for Cause; Executive's Death or Disability.** If Executive's employment is terminated by the Company for Cause or on account of the Executive's Disability, or if Executive's employment is terminated due to the Executive's death, then the Company shall pay Executive all amounts earned or accrued but not paid as of the effective date of such termination, including (i) Executive's then-current base salary; (ii) legitimate business expenses incurred by Executive in the performance of his/her duties to the Company in accordance with the Company's normal policies and practices; (iii) vacation pay in accordance with applicable law and the Company's normal policies and practices; and (iv) any earned or accrued bonus or incentive compensation with respect to the calendar year ended prior to the year in which the termination became effective (collectively, "**Accrued Compensation**").

(b) Termination by Executive without Good Reason. If Executive terminates his/her employment without Good Reason, then the Company will pay Executive all Accrued Compensation earned through the date of such resignation. Nothing herein shall prohibit the Company, in its discretion, from effectuating Executive's resignation sooner than the date set forth in Executive's Notice of Termination.

(c) Termination by the Company without Cause or by Executive for Good Reason (No Change in Control). If Executive's employment is terminated by the Company without Cause or by the Executive for Good Reason where there has not been a Change in Control, and provided that the Executive has satisfied all conditions precedent as set forth herein, then the Company shall:

(i) pay Executive all Accrued Compensation;

(ii) continue paying Executive's then-base salary for a period of twelve (12) months payable in accordance with the normal payroll practices of the Company for its executives generally, with the first such payment to be made on the first payroll date that occurs after the day that is sixty (60) days after the date of termination, retroactive to the date of Executive's termination, or such other method of payment as determined by the Company; and

(iii) provided that Executive appropriately and timely completes all required elections, the Company shall reimburse (on a taxable basis) premiums paid by Executive for health and dental insurance premiums (for himself/herself and all eligible dependents) under the Consolidated Omnibus Budget Reconciliation Act ("COBRA") at the same amount and to the same extent it would if Executive still was employed by the Company until the earliest of (A) the last day of the month which falls twelve (12) months from the date of Executive's termination (or such other period as required by applicable law); (B) the date that Executive and eligible dependents are no longer eligible to receive continuation coverage under COBRA; or (C) the date Executive becomes eligible to receive health or dental care coverage pursuant to the health or dental care plan of a new employer.

In the event that the Company terminates Executive's employment without Cause as set forth in this Section 3(c), but the Company determines within one (1) year of such termination that the Company had the right to terminate Executive's employment for Cause pursuant to Sections 1(a) and 3(a) above, the Company may terminate the payment of any amounts still owed to Executive pursuant to this Section 3(c).

(d) Termination by the Company without Cause or by Executive for Good Reason (Change in Control). If Executive's employment is terminated by the Company without Cause or by Executive for Good Reason, and provided that such termination occurs within twelve (12) months after the occurrence of such qualifying event giving rise to the Change in Control; then the Company shall:

(i) pay Executive all Accrued Compensation;



(ii) continue paying Executive's then-base salary for a period of twelve (12) months payable in accordance with the normal payroll practices of the Company for its executives generally, with the first such payment to be made on the first payroll date that occurs after the day that is sixty (60) days after the date of termination, retroactive to the date of Executive's termination, or such other method of payment as determined by the Company;

(iii) pay Executive an amount equal to fifty percent (50%) of his/her annual target bonus for the year in which the termination occurs, pro-rated to reflect the month in which the termination occurs, such amount to be payable in a lump-sum on the date that is the day that is sixty (60) days after the date of termination; and

(iv) provided that Executive appropriately and timely completes all required elections, the Company shall reimburse (on a taxable basis) premiums paid by Executive for health and dental insurance premiums (for himself/herself and all eligible dependents) under COBRA at the same amount and to the same extent it would if Executive still was employed by the Company until the earliest of (A) the last day of the month which falls twelve (12) months from the date of Executive's termination (or such other period as required by applicable law); (B) the date that Executive and eligible dependents are no longer eligible to receive continuation coverage under COBRA; or (C) the date Executive becomes eligible to receive health or dental care coverage pursuant to the health or dental care plan of a new employer.

In the event that the Company terminates Executive's employment without Cause as set forth in this Section 3(d), but the Company determines within one (1) year of such termination that the Company had the right to terminate Executive's employment for Cause pursuant to Sections 1(a) and 3(a) above, the Company may terminate the payment of any amounts still owed to Executive pursuant to this Section 3(d).

(e) Notice of Termination Required. Any purported termination by the Company or by Executive must be communicated by a written Notice of Termination to the other party. For purposes of this Agreement, no purported termination of employment will be effective without a Notice of Termination.

(f) Timing of Payments. The Accrued Compensation payable to Executive as provided in this Section 3 will be paid pursuant to applicable state law or within ten (10) business days after the effective date of Executive's employment termination, whichever period is shorter. Any other compensation provided for in this Section 3 will be paid as set forth above, subject to Section 9 below.

(g) Payroll Taxes and Withholdings. All Severance Benefits provided for in this Section 3 shall, to the extent required, be subject to ordinary and required payroll taxes, deductions and income tax withholding.

(h) Reemployment. If Executive becomes reemployed by the Company prior to the end of the period in which Executive is entitled to receive Severance Benefits, Executive will no longer be entitled to receive such Severance Benefits (except for any Accrued Compensation) as of the effective date of such reemployment.

(i) Benefit Plans. Executive's entitlement to any other compensation or benefits upon termination of his/her employment shall be determined in accordance with the Company's employee benefit plans and other applicable programs and practices then in effect.

**4. Conditions Precedent to Receipt of Severance Benefits.** Executive shall not be entitled to receive (or continue to receive) any Severance Benefits, except for Accrued Compensation, and shall not be entitled to any continued vesting of outstanding equity awards pursuant to Section 5(b) below unless:

(a) Executive executes (prior to the deadline established by the Company), does not revoke and complies with a general release of all claims against the Company and its officers, directors and employees upon terms and in a form reasonably acceptable to the Company;

(b) Executive executes and complies fully with the restrictive covenants agreement between Executive and the Company regarding assignment of intellectual property, confidentiality and non-disclosure, non-competition and non-solicitation; and

(c) Executive complies fully with Section 7 hereof.

**5. Accelerated Vesting of Equity.**

(a) Upon a Change in Control. One hundred percent (100%) of Executive's outstanding unvested options, restricted shares, restricted stock units or other equity-based awards shall immediately vest upon a Change in Control. The exercisability of stock options (or other awards requiring exercise) shall be extended, to the extent feasible and to the extent consistent with applicable law and the terms of the Company's equity plans or programs (each, as in effect from time to time, a "**Company Equity Plan**" and, together, the "**Company Equity Plans**") and the award agreements issued thereunder, beyond any lockup or similar restrictive period set forth in any documents executed in connection with a Change in Control. The Compensation Committee may determine in its reasonable discretion whether it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder between the Company and Executive in order to effect the extended period of exercise contemplated by this Section 5(a). For the avoidance of doubt, no amendment shall be made by the Compensation Committee in furtherance of this Section 5(a) other than in accordance with Section 409A of Internal Revenue Code of 1986, as amended (the "**Code**") and the regulations and guidance issued thereunder.

(b) Upon Termination by the Company without Cause or by Executive for Good Reason. Executive's outstanding unvested options, restricted shares, restricted stock units or other equity-based awards shall remain outstanding and continue to vest in accordance with the terms of the applicable equity agreement(s) for the period of time during which Executive continues to receive Severance Benefits, as if he or she remained employed during such time, in accordance with Section 3(c)(ii) hereof. The Compensation Committee may determine in its reasonable discretion whether it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder existing between the Company and Executive in order to effect the extended period of vesting contemplated by this Section 5(b). For the avoidance of doubt, no amendment shall be made by the Compensation Committee in furtherance of this Section 5(b) other than in accordance with Code Section 409A and the regulations and guidance issued thereunder.

**6. Cooperation.** During employment and after the termination of Executive's employment for any reason, Executive agrees to cooperate with, and at the request of, the Company in the defense or prosecution of any legal matter or claim in which the Company, any of its affiliates, or any of their past or present employees, agents, officers, directors, attorneys, successors or assigns, may be or become involved and which arises or arose during Executive's employment, to the extent such cooperation does not unreasonably interfere with Executive's personal or professional schedule. Executive will be reimbursed for any reasonable out-of-pocket expenses incurred thereby.

**7. Non-Disparagement.** Executive agrees that during his/her employment and for the greater of (A) one (1) year following the termination of his/her employment (regardless of the reason for

termination) or (B) the period during which Executive receives Severance Benefits hereunder, Executive will not make any statements that are disparaging about or adverse to the business interests of the Company or which are intended to harm the reputation of the Company including, but not limited to, any statements that disparage any product, service, finances, employees, officers, directors, capabilities or any other aspect of the Company's business, products or services.

#### **8. Successors and Assigns.**

(a) **Assignment by Company.** The Company may, without the consent of Executive, assign this Agreement or delegate its obligations hereunder to any firm, entity, company or person (collectively, a "**Person**") in the event that the Company shall hereafter effect a reorganization, consolidate with, or merge into, such Person or transfer all or substantially all of its properties or assets to such Person.

(b) **Assignment by Executive.** Neither this Agreement nor any right or interest hereunder will be assignable or transferable by Executive, his/her beneficiaries or legal representatives, except by will or by the laws of descent and distribution. All payments under this Agreement will inure to the benefit of and be enforceable by Executive's legal personal representative(s).

#### **9. Tax Consequences.**

(a) The Company does not guarantee the tax treatment or tax consequences associated with Severance Benefits received by Executive hereunder.

(b) **Parachute Payments.** To the extent consistent with applicable law, the payment of any amounts or the provision of any benefits under this Agreement including, without limitation, the payment of Severance Benefits pursuant to Section 3 above or the accelerated vesting of equity pursuant to Section 5 above, will be reduced or adjusted to avoid triggering the excise tax imposed by Section 4999 of the Code, if such adjustment would result in the provision of a greater total benefit, on a net after-tax basis (after taking into account taking any applicable federal, state and local income taxes and the excise tax imposed by Section 4999), to Executive.

(c) **Section 409A.** The provisions of this Agreement are intended to comply with the requirements of Code Section 409A or with the conditions for an exemption from such requirements, and shall be construed accordingly. Notwithstanding any provision of this Agreement to the contrary, if at the time of Executive's separation from service (as defined below) Executive is a specified employee (as defined below), as determined by the Company, any and all amounts payable in connection with such separation from service that constitute deferred compensation subject to Code Section 409A, as determined by the Company, and that would otherwise be payable within six (6) months following such separation from service, shall instead be paid on the date that follows the date of such separation from service by six (6) months (or, if earlier, upon the Executive's death). For purposes of this Agreement, all references to "termination of employment" and correlative phrases shall be construed to require a "separation from service" (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained therein), and the term "specified employee" means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

Each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments.

Any reimbursement for expenses that would constitute nonqualified deferred compensation subject to Section 409A shall be subject to the following additional rules: (i) no reimbursement of any such expense shall affect Executive's right to reimbursement of any such expense in any other taxable

year; (ii) reimbursement of the expense shall be made, if at all, promptly, but not later than the end of the calendar year following the calendar year in which the expense was incurred; and (iii) the right to reimbursement shall not be subject to liquidation or exchange for any other benefit.

**10. Notices.** All notices, requests, demands, and other communications called for hereunder will be in writing and will be deemed given (a) on the date of delivery if delivered personally, (b) one (1) day after being sent overnight by a well-established commercial overnight service, or (c) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

Akebia Therapeutics, Inc.  
Attention: General Counsel  
245 First Street, Suite 1100  
Cambridge, Massachusetts 02142

If to Executive:

at the last residential address known by the Company

**11. Non-Exclusivity of Rights.** Nothing in this Agreement will prevent or limit Executive's continuing or future participation in any benefit, bonus, incentive or other plan or program provided by the Company or any of its subsidiaries and for which Executive may qualify, nor will anything herein limit or reduce such rights as Executive may have under any other agreements with the Company or any of its subsidiaries. Amounts which are vested benefits or which Executive is otherwise entitled to receive under any plan or program of the Company or any of its subsidiaries will be payable in accordance with such plan or program, except as explicitly modified by this Agreement.

**12. Amendments.** No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by Executive and the Chief Executive Officer of the Company.

**13. No Waiver.** No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party will be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time.

**14. Governing Law.** This Agreement will be governed by and construed and enforced in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of law principles thereof.

**15. Dispute Resolution/Jurisdiction/Venue.** Any dispute concerning this Agreement shall be heard by a court of competent jurisdiction within Massachusetts. The parties hereby acknowledge that they are subject to the personal jurisdiction of the Massachusetts courts in any county where the Company has operations or facilities and/or Executive resides.

**16. Expenses.** To the extent Executive elects to have independent legal counsel review and or negotiate the terms of this Agreement or any release required by this Agreement, Executive shall be solely responsible for all associated costs and fees, including but not limited to attorneys' fees.

**17. Severability.** The provisions of this Agreement will be deemed severable and the invalidity or unenforceability of any provision will not affect the validity or enforceability of the other provisions hereof.

**18. Effect on Other Agreements.** The terms of this Agreement replace and supersede the terms in all other and prior agreements between Executive and the Company that relate to (i) post-separation severance and other post-separation benefits and (ii) equity acceleration in connection with a change of control, whether written or oral or express or implied, and no representations, promises, assurances or agreements have been made regarding the subject matter of this Agreement, except such as has been stated in this Agreement. For the avoidance of doubt, (a) the terms of any existing employment agreement or other agreement between Executive and the Company regarding assignment of intellectual property, confidentiality and non-disclosure, non-competition and non-solicitation between Executive and the Company shall remain in full force and effect and (b) all other terms in offer letters, employment agreements or any other agreements between Executive and the Company that do not relate to (1) post-separation severance or other post-separation benefits or (2) equity acceleration in connection with a change of control, will remain in full force and effect.

THE COMPANY AND EXECUTIVE ACKNOWLEDGE THAT (A) EACH HAS CAREFULLY READ THIS AGREEMENT, (B) EACH UNDERSTANDS ITS TERMS, (C) ALL UNDERSTANDINGS AND AGREEMENTS BETWEEN THE COMPANY AND EXECUTIVE RELATING TO THE SUBJECTS COVERED IN THIS AGREEMENT ARE CONTAINED IN IT, AND (D) EACH HAS ENTERED INTO THIS AGREEMENT VOLUNTARILY AND NOT IN RELIANCE ON ANY PROMISES OR REPRESENTATIONS BY THE OTHER, OTHER THAN THOSE CONTAINED IN THIS AGREEMENT ITSELF.

**IN WITNESS WHEREOF**, the Company has caused this Agreement to be executed by its duly authorized person and Executive has executed this Agreement effective as of the day and year first above written.

**EXECUTIVE**

By: \_\_\_\_\_  
[NAME]

**AKEBIA THERAPEUTICS, INC.**

By: \_\_\_\_\_  
John P. Butler  
Chief Executive Officer

**EXECUTIVE SEVERANCE AGREEMENT**

This **EXECUTIVE SEVERANCE AGREEMENT** (the “*Agreement*”) is entered into as of the \_\_\_\_\_ day of \_\_\_\_\_, 2014 (the “*Effective Date*”), by and between **Akebia Therapeutics, Inc.**, a Delaware corporation (“*Akebia*” or the “*Company*”), and [FULL LEGAL NAME], a resident of the [State] [Commonwealth] of (the “*Executive*”).

**WHEREAS**, Executive is a valued employee of the Company; and

**WHEREAS**, the Company desires to provide certain severance benefits to Executive according to, and contingent upon, the terms and conditions stated herein (the “*Severance Benefits*”).

**NOW, THEREFORE**, in consideration of the foregoing and the mutual promises contained herein, and of other good and valuable consideration, including the compensation to be received by Executive from the Company from time to time, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

**1. Definitions.**

(a) Cause. For purposes of this Agreement, and in each case as determined by the Compensation Committee of the Company’s Board of Directors (the “*Compensation Committee*”) in its sole and reasonable discretion, the following will constitute “*Cause*”:

- (i) indictment or conviction for either any felony offense or any other crime involving dishonesty;
- (ii) participation in any fraud, theft, embezzlement or other misconduct or act of dishonesty involving the Company or any of its subsidiaries;
- (iii) intentional damage to any property of the Company or any of its subsidiaries;
- (iv) breach of the holder’s duties of good faith and fair dealing that are owed to the Company or any of its subsidiaries;
- (v) breach or violation of any agreement between Executive and the Company or any of its subsidiaries, including, without limitation, any employment, confidentiality, non-competition, non-solicitation or assignment of inventions agreement;
- (vi) conduct which in the good faith and reasonable determination of the Board of Directors demonstrates gross unfitness to serve;
- (vii) failure to comply with the code of conduct of the Company or any of its subsidiaries or any other policies of the Company that have been approved by the Board of Directors or its authorized delegate,
- (viii) insubordination or failure to follow the directions of the Board of Directors or of the Chief Executive Officer or President of the Company; or
- (ix) any other conduct by Executive that could be expected to be harmful to the business, interests or reputation of the Company or any of its subsidiaries.

Executive shall have thirty (30) days after notice from the Company to cure the deficiency leading to the Cause determination (except with respect to Sections 1(a)(i) and 1(a)(ii) above, for which no notice is required) if, in the sole and reasonable discretion of the Compensation Committee, such deficiency is curable.

(b) **Good Reason.** For purposes of this Agreement the following will constitute “**Good Reason**” for Executive to terminate his/her employment with the Company. For the avoidance of doubt, Executive shall not be considered to have terminated his/her employment for Good Reason unless Executive has (A) reasonably determined in good faith that a Good Reason condition has occurred; (B) not consented to the occurrence that s/he alleges constitutes Good Reason; (C) given the Company written Notice of Termination for Good Reason not more than sixty (60) days after the initial existence of the alleged condition giving rise to Good Reason; (D) given the Company at least thirty (30) days after receipt of such notice to cure the alleged deficiency; and (E) terminated his/her employment within sixty (60) days following the Company’s receipt of such notice.

(i) a material reduction in the nature or status of Executive’s responsibilities, authority, position or duties (unless arising directly or indirectly in connection with a documented and significant performance issue in Executive’s then-current position, as determined by the Compensation Committee in its sole and reasonable discretion). Notwithstanding the foregoing, neither of the following shall constitute Good Reason: (A) a reassignment of Executive to a position within the Company of substantially equivalent level or status with respect to Executive’s responsibilities and duties existing immediately prior to such reassignment, or (B) a change in reporting structure;

(ii) a material adverse reduction in the amount of aggregate cash compensation provided to Executive or failure by the Company to pay such compensation, except where such reduction occurs contemporaneously with the implementation of a firm-wide cost-reduction program affecting comparable executives (a “**Reduction Program**”);

(iii) the failure by the Company to continue in effect any incentive compensation plan in which Executive participates, unless an equitable alternative compensation arrangement has been provided, except that to the extent that participation in such plans has been reduced or eliminated for all other eligible executives, in which case the failure to continue Executive in any such plan shall not constitute Good Reason; or

(iv) establishment of the Company’s primary operations in any place beyond a fifty (50) mile radius of Cambridge, Massachusetts; provided, that Executive primarily provides services in Cambridge at the time of such establishment.

In all respects, the definition of Good Reason shall be interpreted to comply with Code Section 409A, and any successor statute, regulation and guidance thereto.

(c) **Change in Control.** For purposes of this Agreement, a “**Change in Control**” means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company’s securities:

(i) any “person” (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the “beneficial owner” (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company’s then outstanding voting securities;

(ii) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors. "Incumbent Directors" will mean directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company);

(iii) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or

(iv) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets.

Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (a) its sole purpose is to change the domicile of the Company's incorporation; or (b) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

In all respects, the definition of Change in Control shall be interpreted to comply with Code Section 409A, and any successor statute, regulation and guidance thereto.

(d) **Notice of Termination.** For purposes of this Agreement, a "**Notice of Termination**" means a notice which, if applicable, sets forth the specific "cause" or "good reason" provision of this Section 2 and sets forth the effective date of termination.

(e) **Disability.** For purposes of this Agreement, "**Disability**" means Executive's inability by reason of physical or mental impairment to perform his/her job duties for a period exceeding twelve (12) consecutive weeks.

**2. Termination of Agreement.** This Agreement will terminate automatically upon (a) Executive's termination for Cause; (b) mutual agreement between the Company and Executive; (c) Executive's death, or (d) Executive's Disability. Upon termination of this Agreement, Executive or his/her heirs or estate (as applicable) only will be entitled to payments required by law or agreement and benefits afforded under the Company's employee benefit plans existing at the time of termination and in which the Executive participates.

**3. Severance Benefits Upon Termination of Executive's Employment.** If Executive's employment is terminated, then s/he may be entitled to certain monetary and non-monetary compensation and benefits as set forth below (the "**Severance Benefits**");

(a) **Termination by the Company for Cause; Executive's Death or Disability.** If Executive's employment is terminated by the Company for Cause or on account of the Executive's Disability, or if Executive's employment is terminated due to the Executive's death, then the Company shall pay Executive all amounts earned or accrued but not paid as of the effective date of such termination, including (i) Executive's then-current base salary; (ii) legitimate business expenses incurred by Executive in the performance of his/her duties to the Company in accordance with the Company's normal policies and practices; (iii) vacation pay in accordance with applicable law and the Company's normal policies and practices; and (iv) any earned or accrued bonus or incentive compensation with respect to the calendar year ended prior to the year in which the termination became effective (collectively, "**Accrued Compensation**").



(b) Termination by Executive without Good Reason. If Executive terminates his/her employment without Good Reason, then the Company will pay Executive all Accrued Compensation earned through the date of such resignation. Nothing herein shall prohibit the Company, in its discretion, from effectuating Executive's resignation sooner than the date set forth in Executive's Notice of Termination.

(c) Termination by the Company without Cause or by Executive for Good Reason (No Change in Control). If Executive's employment is terminated by the Company without Cause or by the Executive for Good Reason where there has not been a Change in Control, and provided that the Executive has satisfied all conditions precedent as set forth herein, then the Company shall:

(i) pay Executive all Accrued Compensation;

(ii) continue paying Executive's then-base salary for a period of nine (9) months payable in accordance with the normal payroll practices of the Company for its executives generally, with the first such payment to be made on the first payroll date that occurs after the day that is sixty (60) days after the date of termination, retroactive to the date of Executive's termination, or such other method of payment as determined by the Company; and

(iii) provided that Executive appropriately and timely completes all required elections, the Company shall reimburse (on a taxable basis) premiums paid by Executive for health and dental insurance premiums (for himself/herself and all eligible dependents) under the Consolidated Omnibus Budget Reconciliation Act ("**COBRA**") at the same amount and to the same extent it would if Executive still was employed by the Company until the earliest of (A) the last day of the month which falls nine (9) months from the date of Executive's termination (or such other period as required by applicable law); (B) the date that Executive and eligible dependents are no longer eligible to receive continuation coverage under COBRA; or (C) the date Executive becomes eligible to receive health or dental care coverage pursuant to the health or dental care plan of a new employer.

In the event that the Company terminates Executive's employment without Cause as set forth in this Section 3(c), but the Company determines within one (1) year of such termination that the Company had the right to terminate Executive's employment for Cause pursuant to Sections 1(a) and 3(a) above, the Company may terminate the payment of any amounts still owed to Executive pursuant to this Section 3(c).

(d) Termination by the Company without Cause or by Executive for Good Reason (Change in Control). If Executive's employment is terminated by the Company without Cause or by Executive for Good Reason, and provided that such termination occurs within twelve (12) months after the occurrence of such qualifying event giving rise to the Change in Control; then the Company shall:

(i) pay Executive all Accrued Compensation;

(ii) continue paying Executive's then-base salary for a period of twelve (12) months payable in accordance with the normal payroll practices of the Company for its executives generally, with the first such payment to be made on the first payroll date that occurs after the day that is sixty (60) days after the date of termination, retroactive to the date of Executive's termination, or such other method of payment as determined by the Company;

(iii) pay Executive an amount equal to fifty percent (50%) of his/her annual target bonus for the year in which the termination occurs, pro-rated to reflect the month in which the termination occurs, such amount to be payable in a lump-sum on the date that is the day that is sixty (60) days after the date of termination; and

(iv) provided that Executive appropriately and timely completes all required elections, the Company shall reimburse (on a taxable basis) premiums paid by Executive for health and dental insurance premiums (for himself/herself and all eligible dependents) under COBRA at the same amount and to the same extent it would if Executive still was employed by the Company until the earliest of (A) the last day of the month which falls twelve (12) months from the date of Executive's termination (or such other period as required by applicable law); (B) the date that Executive and eligible dependents are no longer eligible to receive continuation coverage under COBRA; or (C) the date Executive becomes eligible to receive health or dental care coverage pursuant to the health or dental care plan of a new employer.

In the event that the Company terminates Executive's employment without Cause as set forth in this Section 3(d), but the Company determines within one (1) year of such termination that the Company had the right to terminate Executive's employment for Cause pursuant to Sections 1(a) and 3(a) above, the Company may terminate the payment of any amounts still owed to Executive pursuant to this Section 3(d).

(e) Notice of Termination Required. Any purported termination by the Company or by Executive must be communicated by a written Notice of Termination to the other party. For purposes of this Agreement, no purported termination of employment will be effective without a Notice of Termination.

(f) Timing of Payments. The Accrued Compensation payable to Executive as provided in this Section 3 will be paid pursuant to applicable state law or within ten (10) business days after the effective date of Executive's employment termination, whichever period is shorter. Any other compensation provided for in this Section 3 will be paid as set forth above, subject to Section 9 below.

(g) Payroll Taxes and Withholdings. All Severance Benefits provided for in this Section 3 shall, to the extent required, be subject to ordinary and required payroll taxes, deductions and income tax withholding.

(h) Reemployment. If Executive becomes reemployed by the Company prior to the end of the period in which Executive is entitled to receive Severance Benefits, Executive will no longer be entitled to receive such Severance Benefits (except for any Accrued Compensation) as of the effective date of such reemployment.

(i) Benefit Plans. Executive's entitlement to any other compensation or benefits upon termination of his/her employment shall be determined in accordance with the Company's employee benefit plans and other applicable programs and practices then in effect.

**4. Conditions Precedent to Receipt of Severance Benefits.** Executive shall not be entitled to receive (or continue to receive) any Severance Benefits, except for Accrued Compensation, and shall not be entitled to any continued vesting of outstanding equity awards pursuant to Section 5(b) below unless:

(a) Executive executes (prior to the deadline established by the Company), does not revoke and complies with a general release of all claims against the Company and its officers, directors and employees upon terms and in a form reasonably acceptable to the Company;

(b) Executive executes and complies fully with the restrictive covenants agreement between Executive and the Company regarding assignment of intellectual property, confidentiality and non-disclosure, non-competition and non-solicitation; and

(c) Executive complies fully with Section 7 hereof.

**5. Accelerated Vesting of Equity.**

(a) Upon a Termination by the Company without Cause or by Executive for Good Reason Following a Change in Control. Following a Change in Control, one hundred percent (100%) of Executive's outstanding unvested options, restricted shares, restricted stock units or other equity-based awards shall immediately vest in the event that Executive is terminated by the Company (or the successor company) without Cause or the Executive resigns for Good Reason. Such vesting acceleration shall take place automatically and immediately on the date of such termination of employment without Cause or for Good Reason. The exercisability of stock options (or other awards requiring exercise) shall be extended, to the extent feasible and to the extent consistent with applicable law and the terms of the Company's equity plans or programs (each, as in effect from time to time, a "**Company Equity Plan**" and, together, the "**Company Equity Plans**") and the award agreements issued thereunder, beyond any lockup or similar restrictive period set forth in any documents executed in connection with a Change in Control. The Compensation Committee may determine in its reasonable discretion whether it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder between the Company and Executive in order to effect the extended period of exercise contemplated by this Section 5(a). For the avoidance of doubt, no amendment shall be made by the Compensation Committee in furtherance of this Section 5(a) other than in accordance with Section 409A of Internal Revenue Code of 1986, as amended (the "**Code**") and the regulations and guidance issued thereunder.

(b) Upon Termination by the Company without Cause or by Executive for Good Reason Other than Following a Change in Control. Executive's outstanding unvested options, restricted shares, restricted stock units or other equity-based awards shall remain outstanding and continue to vest in accordance with the terms of the applicable equity agreement(s) for the period of time during which Executive continues to receive Severance Benefits, as if he or she remained employed during such time, in accordance with Section 3(c)(ii) hereof. The Compensation Committee may determine in its reasonable discretion whether it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder existing between the Company and Executive in order to effect the extended period of vesting contemplated by this Section 5(b). For the avoidance of doubt, no amendment shall be made by the Compensation Committee in furtherance of this Section 5(b) other than in accordance with Code Section 409A and the regulations and guidance issued thereunder. For the avoidance of doubt, in the event the termination giving rise to the payment of Severance Benefits occurs following a Change in Control, the acceleration provisions of Section 5(a) above, rather than those of this Section 5(b), shall apply to Executive's outstanding unvested options, restricted shares, restricted stock units or other equity-based awards.

**6. Cooperation.** During employment and after the termination of Executive's employment for any reason, Executive agrees to cooperate with, and at the request of, the Company in the defense or prosecution of any legal matter or claim in which the Company, any of its affiliates, or any of their past or present employees, agents, officers, directors, attorneys, successors or assigns, may be or become involved and which arises or arose during Executive's employment, to the extent such cooperation does not unreasonably interfere with Executive's personal or professional schedule. Executive will be reimbursed for any reasonable out-of-pocket expenses incurred thereby.

**7. Non-Disparagement.** Executive agrees that during his/her employment and for the greater of (A) one (1) year following the termination of his/her employment (regardless of the reason for termination) or (B) the period during which Executive receives Severance Benefits hereunder, Executive will not make any statements that are disparaging about or adverse to the business interests of the Company or which are intended to harm the reputation of the Company including, but not limited to, any statements that disparage any product, service, finances, employees, officers, directors, capabilities or any other aspect of the Company's business, products or services.

**8. Successors and Assigns.**

(a) **Assignment by Company.** The Company may, without the consent of Executive, assign this Agreement or delegate its obligations hereunder to any firm, entity, company or person (collectively, a "**Person**") in the event that the Company shall hereafter effect a reorganization, consolidate with, or merge into, such Person or transfer all or substantially all of its properties or assets to such Person.

(b) **Assignment by Executive.** Neither this Agreement nor any right or interest hereunder will be assignable or transferable by Executive, his/her beneficiaries or legal representatives, except by will or by the laws of descent and distribution. All payments under this Agreement will inure to the benefit of and be enforceable by Executive's legal personal representative(s).

**9. Tax Consequences.**

(a) The Company does not guarantee the tax treatment or tax consequences associated with Severance Benefits received by Executive hereunder.

(b) **Parachute Payments.** To the extent consistent with applicable law, the payment of any amounts or the provision of any benefits under this Agreement including, without limitation, the payment of Severance Benefits pursuant to Section 3 above or the accelerated vesting of equity pursuant to Section 5 above, will be reduced or adjusted to avoid triggering the excise tax imposed by Section 4999 of the Code, if such adjustment would result in the provision of a greater total benefit, on a net after-tax basis (after taking into account taking any applicable federal, state and local income taxes and the excise tax imposed by Section 4999), to Executive.

(c) **Section 409A.** The provisions of this Agreement are intended to comply with the requirements of Code Section 409A or with the conditions for an exemption from such requirements, and shall be construed accordingly. Notwithstanding any provision of this Agreement to the contrary, if at the time of Executive's separation from service (as defined below) Executive is a specified employee (as defined below), as determined by the Company, any and all amounts payable in connection with such separation from service that constitute deferred compensation subject to Code Section 409A, as determined by the Company, and that would otherwise be payable within six (6) months following such separation from service, shall instead be paid on the date that follows the date of such separation from service by six (6) months (or, if earlier, upon the Executive's death). For purposes of this Agreement, all references to "termination of employment" and correlative phrases shall be construed to require a

“separation from service” (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained therein), and the term “specified employee” means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

Each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments.

Any reimbursement for expenses that would constitute nonqualified deferred compensation subject to Section 409A shall be subject to the following additional rules: (i) no reimbursement of any such expense shall affect Executive’s right to reimbursement of any such expense in any other taxable year; (ii) reimbursement of the expense shall be made, if at all, promptly, but not later than the end of the calendar year following the calendar year in which the expense was incurred; and (iii) the right to reimbursement shall not be subject to liquidation or exchange for any other benefit.

**10. Notices.** All notices, requests, demands, and other communications called for hereunder will be in writing and will be deemed given (a) on the date of delivery if delivered personally, (b) one (1) day after being sent overnight by a well-established commercial overnight service, or (c) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

Akebia Therapeutics, Inc.  
Attention: General Counsel  
245 First Street, Suite 1100  
Cambridge, Massachusetts 02142

If to Executive:

at the last residential address known by the Company

**11. Non-Exclusivity of Rights.** Nothing in this Agreement will prevent or limit Executive’s continuing or future participation in any benefit, bonus, incentive or other plan or program provided by the Company or any of its subsidiaries and for which Executive may qualify, nor will anything herein limit or reduce such rights as Executive may have under any other agreements with the Company or any of its subsidiaries. Amounts which are vested benefits or which Executive is otherwise entitled to receive under any plan or program of the Company or any of its subsidiaries will be payable in accordance with such plan or program, except as explicitly modified by this Agreement.

**12. Amendments.** No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by Executive and the Chief Executive Officer of the Company.

**13. No Waiver.** No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party will be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time.

**14. Governing Law.** This Agreement will be governed by and construed and enforced in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of law principles thereof.

**15. Dispute Resolution/Jurisdiction/Venue.** Any dispute concerning this Agreement shall be heard by a court of competent jurisdiction within Massachusetts. The parties hereby acknowledge that they are subject to the personal jurisdiction of the Massachusetts courts in any county where the Company has operations or facilities and/or Executive resides.

**16. Expenses.** To the extent Executive elects to have independent legal counsel review and or negotiate the terms of this Agreement or any release required by this Agreement, Executive shall be solely responsible for all associated costs and fees, including but not limited to attorneys' fees.

**17. Severability.** The provisions of this Agreement will be deemed severable and the invalidity or unenforceability of any provision will not affect the validity or enforceability of the other provisions hereof.

**18. Effect on Other Agreements.** The terms of this Agreement replace and supersede the terms in all other and prior agreements between Executive and the Company that relate to (i) post-separation severance and other post-separation benefits and (ii) equity acceleration in connection with a change of control, whether written or oral or express or implied, and no representations, promises, assurances or agreements have been made regarding the subject matter of this Agreement, except such as has been stated in this Agreement. For the avoidance of doubt, (a) the terms of any existing employment agreement or other agreement between Executive and the Company regarding assignment of intellectual property, confidentiality and non-disclosure, non-competition and non-solicitation between Executive and the Company shall remain in full force and effect and (b) all other terms in offer letters, employment agreements or any other agreements between Executive and the Company that do not relate to (1) post-separation severance or other post-separation benefits or (2) equity acceleration in connection with a change of control, will remain in full force and effect.

THE COMPANY AND EXECUTIVE ACKNOWLEDGE THAT (A) EACH HAS CAREFULLY READ THIS AGREEMENT, (B) EACH UNDERSTANDS ITS TERMS, (C) ALL UNDERSTANDINGS AND AGREEMENTS BETWEEN THE COMPANY AND EXECUTIVE RELATING TO THE SUBJECTS COVERED IN THIS AGREEMENT ARE CONTAINED IN IT, AND (D) EACH HAS ENTERED INTO THIS AGREEMENT VOLUNTARILY AND NOT IN RELIANCE ON ANY PROMISES OR REPRESENTATIONS BY THE OTHER, OTHER THAN THOSE CONTAINED IN THIS AGREEMENT ITSELF.

**IN WITNESS WHEREOF**, the Company has caused this Agreement to be executed by its duly authorized person and Executive has executed this Agreement effective as of the day and year first above written.

**EXECUTIVE**

**AKEBIA THERAPEUTICS, INC.**

By: \_\_\_\_\_  
[NAME]

By: \_\_\_\_\_  
John P. Butler  
Chief Executive Officer

**AKEBIA THERAPEUTICS, INC.**  
**2014 INCENTIVE PLAN**

**1. DEFINED TERMS**

Exhibit A, which is incorporated by reference, defines the terms used in the Plan and sets forth certain operational rules related to those terms.

**2. PURPOSE**

The Plan has been established to advance the interests of the Company by providing for the grant to Participants of Stock-based and other incentive Awards.

**3. ADMINISTRATION**

The Administrator has discretionary authority, subject only to the express provisions of the Plan, to interpret the Plan; determine eligibility for and grant Awards; determine, modify or waive the terms and conditions of any Award; prescribe forms, rules and procedures relating to the Plan; and otherwise do all things necessary or appropriate to carry out the purposes of the Plan. Determinations of the Administrator made under the Plan will be conclusive and will bind all parties.

**4. LIMITS ON AWARDS UNDER THE PLAN**

**(a) Number of Shares.** The maximum number of shares of Stock that may be delivered in satisfaction of Awards under the Plan is 1,020,000 shares, plus 111,937 shares of Stock that are available for grant under the Akebia Therapeutics, Inc. Amended and Restated Equity Incentive Plan as of the date of the adoption of the Plan (the "Share Pool"). The Share Pool shall be automatically increased on January 1 of each calendar year, beginning with the 2015 calendar year and ending with the 2024 calendar year, by an amount equal to three percent (3%) of the number of shares of Stock outstanding on a fully diluted basis as of the close of business on the immediately preceding December 31 (calculated by adding to the number of shares of Stock outstanding, all outstanding securities convertible into Stock on such date on an as converted basis). Notwithstanding the foregoing, the Board may act prior to January 1 of a given year to provide that there will be no such automatic increase in the Share Pool for such year or that the increase in the Share Pool for such year will be a lesser number of shares of Stock than would otherwise occur pursuant to the preceding sentence. No more than 1,131,937 shares of Stock may be issued in satisfaction of ISOs awarded under the Plan. Nothing in this Section 4(a) will be construed as requiring that any, or any fixed number of, ISOs be awarded under the Plan. The limits set forth in this Section 4(a) shall be construed to comply with Section 422 of the Code. For purposes of this Section 4(a), the number of shares of Stock delivered in satisfaction of Awards will be determined (i) net of shares of Stock underlying the portion of any Award that is settled in cash or the portion of any Stock Option or SAR that expires, terminates or is forfeited prior to the issuance of Stock thereunder, (ii) by treating as having been delivered the full number of shares covered by any portion of an SAR that is settled in Stock (and not only the number of shares of Stock delivered in settlement) and (iii) by treating as having been delivered any shares withheld from an Award to satisfy the tax withholding obligations with respect to such Award or in payment of the exercise price of an Award requiring exercise. Any shares of Stock that again become available for grant pursuant to this Section 4(a) shall be added back to the Share Pool.

**(b) Type of Shares.** Stock delivered by the Company under the Plan may be authorized but unissued Stock or previously issued Stock acquired by the Company. No fractional shares of Stock will be delivered under the Plan.

**(c) Section 162(m) Limits.** The following additional limits will apply to Awards of the specified type granted to any person in any calendar year:

(1) Stock Options: 500,000 shares of Stock.

(2) SARs: 500,000 shares of Stock.

(3) Awards other than Stock Options or SARs: 167,500 shares of Stock.

In applying the foregoing limits, (i) all Awards of the specified type granted to the same person in the same calendar year will be aggregated and made subject to one limit; (ii) the limits applicable to Stock Options and SARs refer to the number of shares of Stock subject to those Awards; and (iii) the share limit under clause (3) refers to the maximum number of shares of Stock that may be delivered, or the value of which could be paid in cash or other property, under an Award or Awards of the type specified in clause (3) assuming a maximum payout. The foregoing provisions will be construed in a manner consistent with Section 162(m), including, without limitation, where applicable, the rules under Section 162(m) pertaining to permissible deferrals of exempt awards.

## 5. ELIGIBILITY AND PARTICIPATION

The Administrator will select Participants from among key Employees and directors of, and consultants and advisors to, the Company and its Affiliates. Eligibility for ISOs is limited to individuals described in the first sentence of this Section 5 who are employees of the Company or of a “parent corporation” or “subsidiary corporation” of the Company as those terms are defined in Section 424 of the Code. Eligibility for Stock Options other than ISOs is limited to individuals described in the first sentence of this Section 5 who are providing direct services on the date of grant of the Stock Option to the Company or to a subsidiary of the Company that would be described in the first sentence of Treas. Regs. §1.409A-1(b)(5)(iii)(E).

## 6. RULES APPLICABLE TO AWARDS

### (a) All Awards.

**(1) Award Provisions.** The Administrator will determine the terms of all Awards, subject to the limitations provided herein. By accepting (or, under such rules as the Administrator may prescribe, being deemed to have accepted) an Award, the Participant will be deemed to have agreed to the terms of the Award and the Plan. Notwithstanding any provision of this Plan to the contrary, awards of an acquired company that are converted, replaced or adjusted in connection with the acquisition may contain terms and conditions that are inconsistent with the terms and conditions specified herein, as determined by the Administrator



**(2) Term of Plan.** No Awards may be made after ten years from the Date of Adoption, but previously granted Awards may continue beyond that date in accordance with their terms.

**(3) Transferability.** Neither ISOs nor, except as the Administrator otherwise expressly provides in accordance with the third sentence of this Section 6(a)(3), other Awards may be transferred other than by will or by the laws of descent and distribution. During a Participant's lifetime, ISOs (and, except as the Administrator otherwise expressly provides in accordance with the third sentence of this Section 6(a)(3), SARs and NSOs) may be exercised only by the Participant. The Administrator may permit the gratuitous transfer (*i.e.*, transfer not for value) of Awards other than ISOs to any transferee eligible to be covered by the provisions of Form S-8 (under the Securities Act of 1933), subject to such limitations as the Administrator may impose.

**(4) Vesting, etc.** The Administrator will determine the time or times at which an Award will vest or become exercisable and the terms on which a Stock Option or SAR will remain exercisable. Without limiting the foregoing, the Administrator may at any time accelerate the vesting or exercisability of an Award, regardless of any adverse or potentially adverse tax or other consequences resulting from such acceleration. Unless the Administrator expressly provides otherwise, however, the following rules will apply if a Participant's Employment ceases:

**(A)** Subject to (B) and (C) below, all Stock Options and SARs held by the Participant or the Participant's permitted transferees, if any, immediately prior to the cessation of the Participant's Employment, to the extent then vested and exercisable, will remain exercisable for the lesser of (i) a period of three months or (ii) the period ending on the latest date on which such Stock Option or SAR could have been exercised without regard to this Section 6(a)(4), and will thereupon immediately terminate.

**(B)** All Stock Options and SARs held by a Participant or the Participant's permitted transferees, if any, immediately prior to the cessation of the Participant's Employment due to his or her death, to the extent then vested and exercisable, will remain exercisable for the lesser of (i) the one year period ending with the first anniversary of the Participant's death or (ii) the period ending on the latest date on which such Stock Option or SAR could have been exercised without regard to this Section 6(a)(4), and will thereupon immediately terminate.

**(C)** All Stock Options and SARs (whether or not vested and exercisable) held by a Participant or the Participant's permitted transferees, if any, immediately prior to the cessation of the Participant's Employment will immediately terminate upon such cessation of Employment if the termination is for Cause or occurs in circumstances that in the sole determination of the Administrator would have constituted grounds for the Participant's Employment to be terminated for Cause.

**(D)** Except as provided in (A) and (B) above, immediately upon the cessation of the Participant's Employment, each Stock Option and SAR that is then held by the Participant or by the Participant's permitted transferees, if any, will cease to be

exercisable and will terminate and all other Awards that are then held by the Participant or by the Participant's permitted transferees, if any, to the extent not already vested will be forfeited.

**(5) Additional Restrictions.** The Administrator may cancel, rescind, withhold or otherwise limit or restrict any Award at any time if the Participant is not in compliance with all applicable provisions of the Award agreement and the Plan, or if the Participant breaches any agreement with the Company or its Affiliates with respect to non-competition, non-solicitation, confidentiality or invention assignment. Without limiting the generality of the foregoing, the Administrator may recover Awards made under the Plan and payments under or gain in respect of any Award in accordance with any applicable Company clawback or recoupment policy, as such policy may be in effect from time to time or as otherwise required by applicable law or applicable stock exchange listing standards, including, without limitation, Section 10D of the Exchange Act.

**(6) Taxes.** The delivery, vesting and retention of Stock, cash or other property under an Award are conditioned upon full satisfaction by the Participant of all tax withholding requirements with respect to the Award. The Administrator will prescribe such rules for the withholding of taxes as it deems necessary. The Administrator may, but need not, hold back shares of Stock from an Award or permit a Participant to tender previously owned shares of Stock in satisfaction of tax withholding requirements (but not in excess of the minimum withholding required by law). Each Participant shall enter into and abide by such agreements, plans or programs as the Company may require to effectuate such withholding (including, without limitation, any agreement, plan or program that facilitates the ability of Participant to satisfy his or her obligations under this paragraph by payment to the Company of cash proceeds from the sale of previously acquired shares of Stock), and shall otherwise fully cooperate with the Company in satisfying his or her obligations under this paragraph.

**(7) Dividend Equivalents, Etc.** The Administrator may provide for the payment of amounts (on terms and subject to conditions established by the Administrator) in lieu of cash dividends or other cash distributions with respect to Stock subject to an Award whether or not the holder of such Award is otherwise entitled to share in the actual dividend or distribution in respect of such Award. Any entitlement to dividend equivalents or similar entitlements will be established and administered either consistent with an exemption from, or in compliance with, the requirements of Section 409A. Dividends or dividend equivalent amounts payable in respect of Awards that are subject to restrictions may be subject to such limits or restrictions as the Administrator may impose.

**(8) Rights Limited.** Nothing in the Plan will be construed as giving any person the right to continued employment or service with the Company or its Affiliates, or any rights as a stockholder except as to shares of Stock actually issued under the Plan. The loss of existing or potential profit in Awards will not constitute an element of damages in the event of termination of Employment for any reason, even if the termination is in violation of an obligation of the Company or any Affiliate to the Participant.

**(9) Section 162(m).** In the case of any Performance Award (other than a Stock Option or SAR) intended to qualify for the performance-based compensation exception

under Section 162(m), the Administrator will establish the applicable Performance Criterion or Criteria in writing no later than ninety (90) days after the commencement of the period of service to which the performance relates (or at such earlier time as is required to qualify the Award as performance-based under Section 162(m)) and, prior to the event or occurrence (grant, vesting or payment, as the case may be) that is conditioned on the attainment of such Performance Criterion or Criteria, will certify whether it or they have been attained. The preceding sentence will not apply to an Award eligible (as determined by the Administrator) for exemption from the limitations of Section 162(m) by reason of the post-initial public offering transition relief in Section 1.162-27(f) of the Treasury Regulations.

**(10) Coordination with Other Plans.** Awards under the Plan may be granted in tandem with, or in satisfaction of or substitution for, other Awards under the Plan or awards made under other compensatory plans or programs of the Company or its Affiliates. For example, but without limiting the generality of the foregoing, awards under other compensatory plans or programs of the Company or its Affiliates may be settled in Stock (including, without limitation, Unrestricted Stock) if the Administrator so determines, in which case the shares delivered will be treated as awarded under the Plan (and will reduce the number of shares thereafter available under the Plan in accordance with the rules set forth in Section 4). In any case where an award is made under another plan or program of the Company or its Affiliates and such award is intended to qualify for the performance-based compensation exception under Section 162(m), and such award is settled by the delivery of Stock or another Award under the Plan, the applicable Section 162(m) limitations under both the other plan or program and under the Plan will be applied to the Plan as necessary (as determined by the Administrator) to preserve the availability of the Section 162(m) performance-based compensation exception with respect thereto.

**(11) Section 409A.** Each Award will contain such terms as the Administrator determines, and will be construed and administered, such that the Award either qualifies for an exemption from the requirements of Section 409A or satisfies such requirements.

**(12) Fair Market Value.** In determining the fair market value of any share of Stock under the Plan, the Administrator will make the determination in good faith consistent with the rules of Section 422 and Section 409A to the extent applicable.

**(b) Stock Options and SARs.**

**(1) Time And Manner Of Exercise.** Unless the Administrator expressly provides otherwise, no Stock Option or SAR will be deemed to have been exercised until the Administrator receives a notice of exercise (in form acceptable to the Administrator), which may be an electronic notice, signed (including electronic signature in form acceptable to the Administrator) by the appropriate person and accompanied by any payment required under the Award. A Stock Option or SAR exercised by any person other than the Participant will not be deemed to have been exercised until the Administrator has received such evidence as it may require that the person exercising the Award has the right to do so.

**(2) Exercise Price.** The exercise price (or the base value from which appreciation is to be measured) of each Award requiring exercise will be no less than 100% (or

in the case of an ISO granted to a ten-percent shareholder within the meaning of subsection (b)(6) of Section 422, 110%) of the fair market value of the Stock subject to the Award, determined as of the date of grant, or such higher amount as the Administrator may determine in connection with the grant. Except in connection with a corporate transaction involving the Company (which term shall include, without limitation, any stock dividend, stock split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination, or exchange of shares) or as otherwise contemplated by Section 7 of the Plan, the terms of outstanding Stock Options or SARs, as applicable, may not be amended to reduce the exercise prices of such Stock Options or the base values from which appreciation under such SARs are to be measured other than in accordance with the stockholder approval requirements of the NASDAQ Global Market. Fair market value will be determined by the Administrator consistent with the applicable requirements of Section 422 and Section 409A.

**(3) Payment Of Exercise Price.** Where the exercise of an Award is to be accompanied by payment, payment of the exercise price will be by cash or check acceptable to the Administrator, by the Administrator holding back a number of shares of Stock having a fair market value equal to the exercise price in payment of the exercise price of such Award, or by such other legally permissible means, if any, as may be acceptable to the Administrator.

**(4) Maximum Term.** Stock Options and SARs will have a maximum term not to exceed ten (10) years from the date of grant (or five (5) years from the date of grant in the case of an ISO granted to a ten-percent shareholder described in Section 6(b)(2) above); provided, however, that, if a Participant still holding an outstanding but unexercised NSO or SAR ten (10) years from the date of grant (or, in the case of an NSO or SAR with a maximum term of less than ten (10) years, such maximum term) is prohibited by applicable law or a written policy of the Company applicable to similarly situated employees from engaging in any open-market sales of Stock, and if at such time the Stock is publicly traded (as determined by the Administrator), the maximum term of such Award will instead be deemed to expire on the thirtieth (30<sup>th</sup>) day following the date the Participant is no longer prohibited from engaging in such open market sales.

## 7. EFFECT OF CERTAIN TRANSACTIONS

**(a) Mergers, etc.** Except as otherwise provided in an Award agreement, the following provisions will apply in the event of a Covered Transaction:

**(1) Assumption or Substitution.** If the Covered Transaction is one in which there is an acquiring or surviving entity, the Administrator may (but, for the avoidance of doubt, need not) provide (i) for the assumption or continuation of some or all outstanding Awards or any portion thereof or (ii) for the grant of new awards in substitution therefor by the acquiror or survivor or an affiliate of the acquiror or survivor.

**(2) Cash-Out of Awards.** Subject to Section 7(a)(5) below the Administrator may (but, for the avoidance of doubt, need not) provide for payment (a "cash-out"), with respect to some or all Awards or any portion thereof, equal in the case of each affected Award or portion thereof to the excess, if any, of (A) the fair market value of one share of Stock (as determined by the Administrator in its reasonable discretion) times the number of shares of Stock subject to the

Award or such portion, over (B) the aggregate exercise or purchase price, if any, under the Award or such portion (in the case of an SAR, the aggregate base value above which appreciation is measured), in each case on such payment terms (which need not be the same as the terms of payment to holders of Stock) and other terms, and subject to such conditions, as the Administrator determines, it being understood that if the exercise or purchase price (or base value) of an Award is equal to or greater than the fair market value of one share of Stock, the Award may be cancelled with no payment due hereunder.

**(3) Acceleration of Certain Awards.** Subject to Section 7(a)(5) below, the Administrator may (but, for the avoidance of doubt, need not) provide that any Award requiring exercise will become exercisable, in full or in part and/or that the delivery of any shares of Stock remaining deliverable under any outstanding Award of Stock Units (including Restricted Stock Units and Performance Awards to the extent consisting of Stock Units) will be accelerated in full or in part, in each case on a basis that gives the holder of the Award a reasonable opportunity, as determined by the Administrator, following exercise of the Award or the delivery of the shares, as the case may be, to participate as a stockholder in the Covered Transaction.

**(4) Termination of Awards Upon Consummation of Covered Transaction.** Except as the Administrator may otherwise determine in any case, each Award will automatically terminate (and in the case of outstanding shares of Restricted Stock, will automatically be forfeited) upon consummation of the Covered Transaction, other than Awards assumed pursuant to Section 7(a)(1) above.

**(5) Additional Limitations.** Any share of Stock and any cash or other property delivered pursuant to Section 7(a)(2) or Section 7(a)(3) above with respect to an Award may, in the discretion of the Administrator, contain such restrictions, if any, as the Administrator deems appropriate to reflect any performance or other vesting conditions to which the Award was subject and that did not lapse (and were not satisfied) in connection with the Covered Transaction. For purposes of the immediately preceding sentence, a cash-out under Section 7(a)(2) above or acceleration under Section 7(a)(3) above will not, in and of itself, be treated as the lapsing (or satisfaction) of a performance or other vesting condition. In the case of Restricted Stock that does not vest and is not forfeited in connection with the Covered Transaction, the Administrator may require that any amounts delivered, exchanged or otherwise paid in respect of such Stock in connection with the Covered Transaction be placed in escrow or otherwise made subject to such restrictions as the Administrator deems appropriate to carry out the intent of the Plan.

**(b) Changes in and Distributions With Respect to Stock.**

**(1) Basic Adjustment Provisions.** In the event of a stock dividend, stock split or combination of shares (including a reverse stock split), recapitalization or other change in the Company's capital structure that constitutes an equity restructuring within the meaning of FASB ASC 718, the Administrator will make appropriate adjustments to the Share Pool, to the maximum number of shares of Stock that may be delivered in satisfaction of ISOs under the Plan, and to the maximum share limits described in Section 4(c), and will also make appropriate adjustments to the number and kind of shares of stock or securities subject to Awards then outstanding or subsequently granted, any exercise or purchase prices (or base values) relating to Awards and any other provision of Awards affected by such change.

**(2) Certain Other Adjustments.** The Administrator may also make adjustments of the type described in Section 7(b)(1) above to take into account distributions to stockholders other than those provided for in Section 7(a) and 7(b)(1), or any other event, if the Administrator determines that adjustments are appropriate to avoid distortion in the operation of the Plan, having due regard for the qualification of ISOs under Section 422, the requirements of Section 409A, and for the performance-based compensation rules of Section 162(m), where applicable.

**(3) Continuing Application of Plan Terms.** References in the Plan to shares of Stock will be construed to include any stock or securities resulting from an adjustment pursuant to this Section 7.

## **8. LEGAL CONDITIONS ON DELIVERY OF STOCK**

The Company will not be obligated to deliver any shares of Stock pursuant to the Plan or to remove any restriction from shares of Stock previously delivered under the Plan until: (i) the Company is satisfied that all legal matters in connection with the issuance and delivery of such shares have been addressed and resolved; (ii) if the outstanding Stock is at the time of delivery listed on any stock exchange or national market system, the shares to be delivered have been listed or authorized to be listed on such exchange or system upon official notice of issuance; and (iii) all conditions of the Award have been satisfied or waived. The Company may require, as a condition to exercise of the Award, such representations or agreements as counsel for the Company may consider appropriate to avoid violation of the Securities Act of 1933, as amended, or any applicable state or non-U.S. securities law. Any Stock required to be issued to Participants under the Plan will be evidenced in such manner as the Administrator may deem appropriate, including book-entry registration or delivery of stock certificates. In the event that the Administrator determines that Stock certificates will be issued to Participants under the Plan, the Administrator may require that certificates evidencing Stock issued under the Plan bear an appropriate legend reflecting any restriction on transfer applicable to such Stock, and the Company may hold the certificates pending lapse of the applicable restrictions.

## **9. AMENDMENT AND TERMINATION**

The Administrator may at any time or times amend the Plan or any outstanding Award for any purpose which may at the time be permitted by law, and may at any time terminate the Plan as to any future grants of Awards; provided, that except as otherwise expressly provided in the Plan the Administrator may not, without the Participant's consent, alter the terms of an Award so as to affect materially and adversely the Participant's rights under the Award, unless the Administrator expressly reserved the right to do so at the time the Award was granted. Any amendments to the Plan will be conditioned upon stockholder approval only to the extent, if any, such approval is required by law (including the Code and applicable stock exchange requirements), as determined by the Administrator.

## 10. OTHER COMPENSATION ARRANGEMENTS

The existence of the Plan or the grant of any Award will not in any way affect the Company's right to award a person bonuses or other compensation in addition to Awards under the Plan.

## 11. MISCELLANEOUS

**(a) Waiver of Jury Trial.** By accepting an Award under the Plan, each Participant waives any right to a trial by jury in any action, proceeding or counterclaim concerning any rights under the Plan and any Award, or under any amendment, waiver, consent, instrument, document or other agreement delivered or which in the future may be delivered in connection therewith, and agrees that any such action, proceedings or counterclaim will be tried before a court and not before a jury. By accepting an Award under the Plan, each Participant certifies that no officer, representative, or attorney of the Company has represented, expressly or otherwise, that the Company would not, in the event of any action, proceeding or counterclaim, seek to enforce the foregoing waivers. Notwithstanding anything to the contrary in the Plan, nothing herein is to be construed as limiting the ability of the Company and a Participant to agree to submit disputes arising under the terms of the Plan or any Award made hereunder to binding arbitration or as limiting the ability of the Company to require any eligible individual to agree to submit such disputes to binding arbitration as a condition of receiving an Award hereunder.

**(b) Limitation of Liability.** Notwithstanding anything to the contrary in the Plan, neither the Company, nor any Affiliate, nor the Administrator, nor any person acting on behalf of the Company, any Affiliate, or the Administrator, will be liable to any Participant or to the estate or beneficiary of any Participant or to any other holder of an Award by reason of any acceleration of income, or any additional tax (including any interest and penalties), asserted by reason of the failure of an Award to satisfy the requirements of Section 422 or Section 409A or by reason of Section 4999 of the Code, or otherwise asserted with respect to the Award; provided, that nothing in this Section 11(b) will limit the ability of the Administrator or the Company, in its discretion, to provide by separate express written agreement with a Participant for any payment in connection with any such acceleration of income or additional tax.

## 12. ESTABLISHMENT OF SUB-PLANS

The Administrator may from time to time establish one or more sub-plans under the Plan for purposes of satisfying applicable blue sky, securities or tax laws of various jurisdictions. The Administrator will establish such sub-plans by adopting supplements to the Plan setting forth (i) such limitations on the Administrator's discretion under the Plan as it deems necessary or desirable and (ii) such additional terms and conditions not otherwise inconsistent with the Plan as it deems necessary or desirable. All supplements so established will be deemed to be part of the Plan, but each supplement will apply only to Participants within the affected jurisdiction (as determined by the Administrator).

## 13. GOVERNING LAW

**(a) Certain Requirements of Corporate Law.** Awards will be granted and administered consistent with the requirements of applicable Massachusetts law relating to the

issuance of stock and the consideration to be received therefor, and with the applicable requirements of the stock exchanges or other trading systems on which the Stock is listed or entered for trading, in each case as determined by the Administrator.

**(b) Other Matters.** Except as otherwise provided by the express terms of an Award agreement, under a sub-plan described in Section 12 or as provided in Section 13(a) above, the provisions of the Plan and of Awards under the Plan and all claims or disputes arising out of or based upon the Plan or any Award under the Plan or relating to the subject matter hereof or thereof will be governed by and construed in accordance with the domestic substantive laws of the State of Delaware without giving effect to any choice or conflict of laws provision or rule that would cause the application of the domestic substantive laws of any other jurisdiction.

**(c) Jurisdiction.** By accepting an Award, each Participant will be deemed to (a) have submitted irrevocably and unconditionally to the jurisdiction of the federal and state courts located within the geographic boundaries of the United States District Court for the District of Massachusetts for the purpose of any suit, action or other proceeding arising out of or based upon the Plan or any Award; (b) agree not to commence any suit, action or other proceeding arising out of or based upon the Plan or an Award, except in the federal and state courts located within the geographic boundaries of the United States District Court for the District of Massachusetts; and (c) waive, and agree not to assert, by way of motion as a defense or otherwise, in any such suit, action or proceeding, any claim that it is not subject personally to the jurisdiction of the above-named courts that its property is exempt or immune from attachment or execution, that the suit, action or proceeding is brought in an inconvenient forum, that the venue of the suit, action or proceeding is improper or that the Plan or an Award or the subject matter thereof may not be enforced in or by such court.



## EXHIBIT A

### Definition of Terms

The following terms, when used in the Plan, will have the meanings and be subject to the provisions set forth below:

**“Administrator”:** The Compensation Committee, except that the Compensation Committee may delegate (i) to one or more of its members (or one or more other members of the Board (including the full Board)) such of its duties, powers and responsibilities as it may determine; (ii) to one or more officers of the Company the power to grant Awards to the extent permitted by Section 157(c) of the Delaware General Corporation Law; and (iii) to such Employees or other persons as it determines such ministerial tasks as it deems appropriate. In the event of any delegation described in the preceding sentence, the term “Administrator” will include the person or persons so delegated to the extent of such delegation.

**“Affiliate”:** Any corporation or other entity that stands in a relationship to the Company that would result in the Company and such corporation or other entity being treated as one employer under Section 414(b) and Section 414(c) of the Code.

**“Award”:** Any or a combination of the following:

- (i) Stock Options.
- (ii) SARs.
- (iii) Restricted Stock.
- (iv) Unrestricted Stock.
- (v) Stock Units, including Restricted Stock Units.
- (vi) Performance Awards.
- (vii) Awards (other than Awards described in (i) through (vi) above) that are convertible into or otherwise based on Stock.

**“Board”:** The Board of Directors of the Company.

**“Cause”:** In the case of any Participant who is party to an employment, consulting or severance-benefit agreement that contains a definition of “Cause,” the definition set forth in such agreement will apply with respect to such Participant under the Plan. In the case of any other Participant, “Cause” will mean, as determined by the Administrator in its reasonable judgment, (a) indictment or conviction for either any felony offense or any other crime involving dishonesty, (b) participation in any fraud, theft, embezzlement or other misconduct or act of dishonesty involving the Company or any of its Affiliates, (c) intentional damage to any property of the Company or any of its Affiliates, (d) breach of the holder’s duties of good faith and fair dealing that are owed to the Company or any of its Affiliates, (e) breach or violation of any

agreement between the Participant and the Company or any of its Affiliates, including, without limitation, any employment, confidentiality, non-competition, non-solicitation or assignment of inventions agreement, (f) conduct which in the good faith and reasonable determination of the Board demonstrates gross unfitness to serve, (g) failure to comply with the code of conduct of the Company or any of its Affiliates or any other policies of the Company that have been approved by the Board or its authorized delegate, (h) insubordination or failure to follow the directions of the Board or of the Chief Executive Officer or President of the Company or (i) any other conduct by the Participant that could be expected to be harmful to the business, interests or reputation of the Company or any of its Affiliates.

**“Code”:** The U.S. Internal Revenue Code of 1986 as from time to time amended and in effect, or any successor statute as from time to time in effect.

**“Compensation Committee”:** The Compensation Committee of the Board.

**“Company”:** Akebia Therapeutics, Inc.

**“Covered Transaction”:** Any of (i) a consolidation, merger, or similar transaction or series of related transactions, including a sale or other disposition of stock, in which the Company is not the surviving corporation or that results in the acquisition of all or substantially all of the Company’s then outstanding common stock by a single person or entity or by a group of persons and/or entities acting in concert, (ii) a sale or transfer of all or substantially all the Company’s assets, or (iii) a dissolution or liquidation of the Company. Where a Covered Transaction involves a tender offer that is reasonably expected to be followed by a merger described in clause (i) (as determined by the Administrator), the Covered Transaction will be deemed to have occurred upon consummation of the tender offer.

**“Date of Adoption”:** The earlier of the date the Plan was approved by the Company’s stockholders or adopted by the Board, as determined by the Compensation Committee.

**“Employee”:** Any person who is employed by the Company or an Affiliate.

**“Employment”:** A Participant’s employment or other service relationship with the Company and its Affiliates. Employment will be deemed to continue, unless the Administrator expressly provides otherwise, so long as the Participant is employed by, or otherwise is providing services in a capacity described in Section 5 to the Company or an Affiliate. If a Participant’s employment or other service relationship is with an Affiliate and that entity ceases to be an Affiliate, the Participant’s Employment will be deemed to have terminated when the entity ceases to be an Affiliate unless the Participant transfers Employment to the Company or its remaining Affiliates. Notwithstanding the foregoing and the definition of “Affiliate” above, in construing the provisions of any Award relating to the payment of “nonqualified deferred compensation” (subject to Section 409A) upon a termination or cessation of Employment, references to termination or cessation of employment, separation from service, retirement or similar or correlative terms will be construed to require a “separation from service” (as that term is defined in Section 1.409A-1(h) of the Treasury Regulations after giving effect to the presumptions contained therein) from the Company and from all other corporations and trades or businesses, if any, that would be treated as a single “service recipient” with the Company under

Section 1.409A-1(h)(3) of the Treasury Regulations. The Company may, but need not, elect in writing, subject to the applicable limitations under Section 409A, any of the special elective rules prescribed in Section 1.409A-1(h) of the Treasury Regulations for purposes of determining whether a “separation from service” has occurred. Any such written election will be deemed a part of the Plan.

**“Exchange Act”:** The Securities Exchange Act of 1934, as amended from time to time, and any successor thereto.

**“ISO”:** A Stock Option intended to be an “incentive stock option” within the meaning of Section 422. Each Stock Option granted pursuant to the Plan will be treated as providing by its terms that it is to be an NSO unless, as of the date of grant, it is expressly designated as an ISO.

**“NSO”:** A Stock Option that is not intended to be an “incentive stock option” within the meaning of Section 422.

**“Participant”:** A person who is granted an Award under the Plan.

**“Performance Award”:** An Award subject to Performance Criteria. The Administrator in its discretion may grant Performance Awards that are intended to qualify for the performance-based compensation exception under Section 162(m) and Performance Awards that are not intended so to qualify.

**“Performance Criteria”:** Specified criteria, other than the mere continuation of Employment or the mere passage of time, the satisfaction of which is a condition for the grant, exercisability, vesting or full enjoyment of an Award. For purposes of Awards that are intended to qualify for the performance-based compensation exception under Section 162(m), a Performance Criterion will mean an objectively determinable measure or objectively determinable measures of performance relating to any or any combination of the following (measured either absolutely or by reference to an index or indices and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof) : sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, amortization, or equity expense, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital, capital employed or assets; one or more operating ratios; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; stock price; stockholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures, strategic alliances, licenses or collaborations; spin-offs, split-ups and the like; reorganizations; or recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; manufacturing or process development; or achievement of clinical trial or research objectives, regulatory or other filings or approvals or other product development milestones. A Performance Criterion and any targets with respect thereto determined by the Administrator need not be based upon an increase, a positive or improved result or avoidance of loss. To the extent consistent with the requirements for satisfying the performance-based compensation exception under Section 162(m), the Administrator may provide in the case of any Award intended to qualify for such exception that one or more of the Performance Criteria applicable to such Award will be adjusted in an

objectively determinable manner to reflect events (for example, the impact of charges for restructurings, discontinued operations, mergers, acquisitions, extraordinary items, and other unusual or non-recurring items, and the cumulative effects of tax or accounting changes, each as defined by U.S. generally accepted accounting principles) occurring during the performance period that affect the applicable Performance Criterion or Criteria.

**“Plan”**: The Akebia Therapeutics, Inc. 2014 Incentive Plan as from time to time amended and in effect.

**“Restricted Stock”**: Stock subject to restrictions requiring that it be redelivered or offered for sale to the Company if specified conditions are not satisfied.

**“Restricted Stock Unit”**: A Stock Unit that is, or as to which the delivery of Stock or cash in lieu of Stock is, subject to the satisfaction of specified performance or other vesting conditions.

**“SAR”**: A right entitling the holder upon exercise to receive an amount (payable in cash or in shares of Stock of equivalent value) equal to the excess of the fair market value of the shares of Stock subject to the right over the base value from which appreciation under the SAR is to be measured.

**“Section 409A”**: Section 409A of the Code.

**“Section 422”**: Section 422 of the Code.

**“Section 162(m)”**: Section 162(m) of the Code.

**“Stock”**: Common stock of the Company, par value \$0.00001 per share.

**“Stock Option”**: An option entitling the holder to acquire shares of Stock upon payment of the exercise price.

**“Stock Unit”**: An unfunded and unsecured promise, denominated in shares of Stock, to deliver Stock or cash measured by the value of Stock in the future.

**“Unrestricted Stock”**: Stock not subject to any restrictions under the terms of the Award.

**AKEBIA THERAPEUTICS, INC.**  
**2014 EMPLOYEE STOCK PURCHASE PLAN**

**Section 1. Defined Terms**

Exhibit A, which is incorporated by reference, defines the terms used in the Plan and sets forth certain operational rules related to those terms.

**Section 2. Purpose of Plan**

The Plan is intended to enable Eligible Employees of the Company and its Designated Subsidiaries to use payroll deductions to purchase shares of Stock, and thereby acquire an interest in the future of the Company. The Plan is intended to qualify as an "employee stock purchase plan" under Section 423 and to be exempt from the application and requirements of Section 409A of the Code, and is to be construed accordingly.

**Section 3. Options to Purchase Stock**

Subject to adjustment pursuant to Section 16 of the Plan, the maximum aggregate number of shares of Stock available for purchase pursuant to the exercise of Options granted under the Plan to Eligible Employees will be the lesser of (a) 150,000 shares increased on each anniversary of the adoption of the Plan by one percent (1%) of the total shares of Stock then outstanding and (b) 422,635 shares of Stock (which is five percent (5%) of the total shares of Stock outstanding on a fully-diluted, as-converted basis on the date of adoption of the Plan). The shares of Stock to be delivered upon exercise of Options under the Plan may be either shares of authorized but unissued Stock, treasury Stock, or Stock acquired in an open-market transaction. If any Option granted under the Plan expires or terminates for any reason without having been exercised in full or ceases for any reason to be exercisable in whole or in part, the unpurchased shares of Stock subject to such Option will again be available for purchase pursuant to the exercise of Options under the Plan. If, on an Exercise Date, the total number of shares of Stock that would otherwise be subject to Options granted under the Plan exceeds the number of shares then available under the Plan (after deduction of all shares for which Options have been exercised or are then outstanding), the Administrator shall make a pro rata allocation of the shares remaining available for the Option grants in as uniform a manner as shall be practicable and as it shall determine to be equitable. In such event, the Administrator shall give written notice to each Participant of such reduction of the number of Options affected thereby and shall similarly reduce the rate of payroll deductions, if necessary.

**Section 4. Eligibility**

Subject to Section 13 of the Plan, and any exceptions and limitations set forth in Section 6 of the Plan, or as may be provided elsewhere in the Plan, each Employee who (a) has been continuously employed by the Company or a Designated Subsidiary, as applicable, for at least twenty (20) business days as of the first day of any Option Period, (b) customarily works twenty (20) hours or more per week, (c) customarily works for more than 5 months in any calendar year and (d) satisfies the requirements set forth in the Plan, will be an Eligible Employee. In no

event, however, may an Employee be granted an Option under the Plan if, immediately after the Option is granted, the Employee would own (or pursuant to Section 424(d) of the Code would be deemed to own) stock possessing five percent (5%) or more of the total combined voting power or value of all classes of stock of the Company or of its Parent or Subsidiaries, if any. The Administrator may, for Option Periods that have not yet commenced, establish additional eligibility requirements not inconsistent with Section 423.

#### **Section 5. Option Periods**

The Plan will generally be implemented by a series of “**Option Periods**”. Unless otherwise determined by the Administrator, the Option Periods will be the six-month periods commencing on the first trading days of January and July and ending on the last trading days of June and December, respectively, of each year. The last day of each such Option Period will be an “**Exercise Date**”. The Administrator may change the Exercise Date (including the number of Exercise Dates within each Option Period) and the commencement date, ending date and duration of the Option Periods to the extent permitted by Section 423, provided that no Exercise Date will be later than 7 business days after the end of the applicable Option Period.

#### **Section 6. Option Grant**

Subject to the limitations set forth in Section 4 and Section 10 of the Plan and the Maximum Share Limit, on the first day of an Option Period, each Participant automatically will be granted an Option to purchase shares of Stock on the Exercise Date; *provided, however*, that no Participant will be granted an Option under the Plan that permits the Participant’s right to purchase shares of Stock under the Plan and under all other employee stock purchase plans of the Company and its Parent and Subsidiaries, if any, to accrue at a rate that exceeds \$25,000 in Fair Market Value (or such other maximum as may be prescribed from time to time by the Code) for each calendar year during which any Option granted to such Participant is outstanding at any time, as determined in accordance with Section 423(b)(8) of the Code and the regulations promulgated thereunder.

#### **Section 7. Method of Participation**

To participate in an Option Period, an Eligible Employee must execute and deliver to the Administrator a payroll deduction and participation authorization form in accordance with the procedures prescribed by and in a form acceptable to the Administrator and, in so doing, the Eligible Employee will thereby become a Participant as of the first day of such Option Period. Such an Eligible Employee will remain a Participant with respect to subsequent Option Periods until his or her participation in the Plan is terminated as provided herein. Eligible Employees may only participate in one Option Period at a time. Such payroll deduction and participation authorization must be delivered no later than ten (10) business days prior to the first day of an Option Period, or such other time as specified by the Administrator.

A Participant’s authorization will remain in effect for subsequent Option Periods unless the Participant files a new authorization within ten (10) business days prior to the first day of such new Option Period (or such other time as specified by the Administrator) or the Participant’s Option is cancelled pursuant to Section 13 or Section 14 of the Plan. During an

Option Period, payroll deduction authorizations may not be increased and may be decreased only once. To decrease a payroll deduction authorization during an Option Period, a Participant must submit a new authorization, which will become effective as to future pay dates as soon as administratively practicable after such authorization is submitted. For the avoidance of doubt, a Participant may terminate his or her payroll deduction authorization by canceling his or her Option in accordance with Section 13 of the Plan.

Each payroll deduction authorization will request payroll deductions in a whole percentage amount between 1% and 15% of the employee's base pay or salary per payroll period. For the avoidance of doubt, no payroll deductions will be taken pursuant to this Section 7 from any cash compensation other than base pay or salary, including, without limitation, overtime, cash bonuses or commissions.

All payroll deductions made pursuant to this Section 7 will be credited to the Participant's Account. Amounts credited to a Participant's Account will not be required to be set aside in trust or otherwise segregated from the Company's general assets.

**Section 8. Method of Payment**

A Participant must pay for shares of Stock purchased upon the exercise of an Option with accumulated payroll deductions credited to the Participant's Account or such other method as authorized by the Administrator.

**Section 9. Purchase Price**

The Purchase Price of shares of Stock issued pursuant to the exercise of an Option on each Exercise Date will be eighty-five percent (85%) (or such greater percentage specified by the Administrator to the extent permitted under Section 423) of the lesser of (a) the Fair Market Value of a share of Stock on the date on which the Option was granted pursuant to Section 6 of the Plan (*i.e.*, the first day of the Option Period) and (b) the Fair Market Value of a share of Stock on the date on which the Option is deemed exercised pursuant to Section 10 of the Plan (*i.e.*, the Exercise Date).

**Section 10. Exercise of Options**

Subject to the limitations set forth in Section 6 of the Plan and this Section 10, with respect to each Option Period, on the applicable Exercise Date, each Participant will be deemed to have exercised his or her Option and the accumulated payroll deductions in the Participant's Account and such other amounts credited to the Participant's Account in such other method as authorized by the Administrator pursuant to Section 8 above will be applied to purchase the greatest number of whole shares of Stock (rounded down to the nearest whole share) that can be purchased with such Account balance at the applicable Purchase Price; *provided, however*, that no more than 1,500 shares of Stock may be purchased by a Participant on any Exercise Date, or such lesser number as the Administrator may prescribe in accordance with Section 423 (the "**Maximum Share Limit**"). As soon as practicable thereafter, shares of Stock so purchased will be placed, in book-entry form, into a record keeping account in the name of the Participant. No fractional shares will be purchased; any payroll deductions accumulated in a Participant's Account that are not sufficient to purchase a full share will be retained in the Participant's Account for the subsequent Option Period, subject to earlier withdrawal by the Participant as provided in Section 13 of the Plan.

Except as provided above with respect to fractional shares, any amount of payroll deductions in a Participant's Account that are not used for the purchase of shares of Stock, whether because of the Participant's withdrawal from participation in an Option Period or for any other reason, will be returned to the Participant or his or her designated beneficiary or legal representative, as applicable, without interest, as soon as administratively practicable after such withdrawal or other event, as applicable.

If the Participant's accumulated payroll deductions on the Exercise Date would otherwise enable the Participant to purchase shares of Stock in excess of the Maximum Share Limit or the maximum Fair Market Value set forth in Section 6 of the Plan, the excess of the amount of the accumulated payroll deductions over the aggregate Purchase Price of the shares of Stock actually purchased will be returned to the Participant, without interest, as soon as administratively practicable after such Exercise Date.

Notwithstanding any provision of the Plan to the contrary, no Option may be exercised after 27 months from its grant date.

**Section 11. Interest**

No interest will be payable on any amount held in the Account of any Participant.

**Section 12. Taxes**

Payroll deductions will be made on an after-tax basis. The Administrator will have the right, as a condition to exercising an Option, to make such provision as it deems necessary to satisfy its obligations to withhold federal, state, local income or other taxes incurred by reason of the purchase or disposition of shares of Stock under the Plan. In the Administrator's discretion and subject to applicable law, such tax obligations may be paid in whole or in part by delivery of shares of Stock to the Company, including shares of Stock purchased under the Plan, valued at Fair Market Value, but not in excess of the minimum statutory amounts required to be withheld.

**Section 13. Cancellation and Withdrawal**

A Participant who holds an Option under the Plan may cancel all (but not less than all) of his or her Option and terminate his or her payroll deduction authorization by revoking such authorization by written notice delivered to the Administrator, which, to be effective with respect to an upcoming Exercise Date, must be delivered not later than ten (10) business days prior to such Exercise Date (or such other time as specified by the Administrator). Upon such termination and cancellation, the balance in the Participant's Account will be returned to the Participant, without interest, as soon as administratively practicable thereafter. For the avoidance of doubt, a Participant who reduces his or her withholding rate for future payroll periods to zero pursuant to Section 7 of the Plan, will be deemed to have revoked his or her payroll deduction authorization and canceled his or her Option.



A Participant who makes a hardship withdrawal from a 401(k) Plan will be deemed to have terminated his or her payroll deduction authorization for subsequent payroll dates relating to the then current Option Period as of the date of such hardship withdrawal and amounts accumulated in the Participant's Account as of such date will be returned to the Participant, without interest, as soon as administratively practicable thereafter. An Employee who has made a hardship withdrawal from a 401(k) Plan will not be permitted to participate in Option Periods commencing after the date of his or her hardship withdrawal until the first Option Period that begins at least six months after the date of his or her hardship withdrawal.

**Section 14. Termination of Employment; Death of Participant**

Upon the termination of a Participant's employment with the Company (or a Designated Subsidiary, as applicable) for any reason or the death of a Participant during an Option Period prior to an Exercise Date or in the event the Participant ceases to qualify as an Eligible Employee, the Participant will cease to be a Participant, any Option held by him or her under the Plan will be deemed canceled, the balance in the Participant's Account will be returned to the Participant (or his or her estate or designated beneficiary in the event of the Participant's death), without interest, as soon as administratively practicable thereafter, and the Participant will have no further rights under the Plan.

**Section 15. Equal Rights; Participant's Rights Not Transferable**

All Participants granted Options under the Plan will have the same rights and privileges consistent with the requirements set forth in Section 423. Any Option granted under the Plan will be exercisable during the Participant's lifetime only by him or her and may not be sold, pledged, assigned, or transferred in any manner. In the event any Participant violates or attempts to violate the terms of this Section 15, as determined by the Administrator in its sole discretion, any Options held by him or her may be terminated by the Company and, upon the return to the Participant of the balance of his or her Account, without interest, all of the Participant's rights under the Plan will terminate.

**Section 16. Change in Capitalization; Merger**

In the event of any change in the outstanding Stock by reason of a stock dividend, split-up, recapitalization, merger, consolidation, reorganization, or other capital change, the aggregate number and type of shares of Stock available under the Plan, the number and type of shares of Stock granted under any outstanding Options, the maximum number and type of shares of Stock purchasable under any outstanding Option, and the purchase price per share of Stock under any outstanding Option will be appropriately adjusted; *provided*, that any such adjustment shall be made in a manner that complies with Section 423.

In the event of a sale of all or substantially all of the Stock or a sale of all or substantially all of the assets of the Company, or a merger or similar transaction in which the Company is not the surviving corporation or that results in the acquisition of the Company by another person, the Administrator may, in its discretion, (a) if the Company is merged with or acquired by another corporation, provide that each outstanding Option will be assumed or exchanged for a substitute Option granted by the acquiror or successor corporation or by a parent or subsidiary of the

acquiror or successor corporation, (b) cancel each outstanding Option and return the balances in Participants' Accounts to the Participants, and/or (c) pursuant to Section 18 of the Plan, terminate the Option Period on or before the date of the proposed sale, merger or similar transaction.

**Section 17. Administration of Plan**

The Plan will be administered by the Administrator, which will have the authority to interpret the Plan, determine eligibility under the Plan, prescribe forms, rules and procedures relating to the Plan and otherwise do all things necessary or appropriate to carry out the purposes of the Plan. All determinations and decisions by the Administrator regarding the interpretation or application of the Plan will be final and binding on all Participants.

The Administrator may specify the manner in which Employees are to provide notices and payroll deduction authorizations. Notwithstanding any requirement of "written notice" herein, the Administrator may permit Employees to provide notices and payroll deduction authorizations electronically.

**Section 18. Amendment and Termination of Plan**

The Board reserves the right at any time or times to amend the Plan to any extent and in any manner it may deem advisable; *provided*, that any amendment that would be treated as the adoption of a new plan for purposes of Section 423 will have no force or effect unless approved by the shareholders of the Company within 12 months before or after its adoption.

The Board reserves the right at any time or times to suspend or terminate the Plan. In connection therewith, the Board may provide, in its sole discretion, either that outstanding Options will be exercisable either at the Exercise Date for the applicable Option Period or on such earlier date as the Board may specify (in which case such earlier date will be treated as the Exercise Date for the applicable Option Period), or that the balance of each Participant's Account will be returned to the Participant, without interest.

**Section 19. Approvals**

Shareholder approval will be obtained prior to the date that is 12 months after the date of Board approval. In the event that the Plan has not been approved by the shareholders of the Company by such date, all Options to purchase shares of Stock under the Plan will be cancelled and become null and void.

Notwithstanding anything herein to the contrary, the obligation of the Company to issue and deliver shares of Stock under the Plan will be subject to the approval required of any governmental authority in connection with the authorization, issuance, sale or transfer of such shares of Stock and to any requirements of any national securities exchange applicable thereto, and to compliance by the Company with other applicable legal requirements in effect from time to time.

**Section 20. Participants' Rights as Shareholders and Employees**

A Participant will have no rights or privileges as a shareholder of the Company and will not receive any dividends in respect of any shares of Stock covered by an Option granted hereunder until such Option has been exercised, full payment has been made for such shares of Stock, and the shares of Stock have been issued to the Participant.

Nothing contained in the provisions of the Plan will be construed as giving to any Employee the right to be retained in the employ of the Company or any Designated Subsidiary or as interfering with the right of the Company or any Designated Subsidiary to discharge, promote, demote or otherwise re-assign any Employee from one position to another within the Company or any Designated Subsidiary at any time.

**Section 21. Information Regarding Disqualifying Dispositions.**

By electing to participate in the Plan, each Participant agrees to provide such information about any transfer of Stock acquired under the Plan that occurs within two years after the first day of the Option Period in which such Stock was acquired and within one year after the acquisition of such Stock as may be requested by the Company or any Designated Subsidiary in order to assist it in complying with applicable tax laws.

**Section 22. Governing Law**

The Plan will be governed by and interpreted consistently with the laws of the State of Delaware, except as may be necessary to comply with applicable requirements of federal law.

**Section 23. Effective Date and Term**

The Plan will become effective upon adoption of the Plan by the Board and no rights will be granted hereunder after the earliest to occur of (a) the Plan's termination by the Company, (b) the issuance of all shares of Stock available for issuance under the Plan or (c) the day before the 10-year anniversary of the date the Board approves the Plan.

**EXHIBIT A**  
**Definition of Terms**

The following terms, when used in the Plan, will have the meanings and be subject to the provisions set forth below:

**“401(k) Plan”**: A savings plan qualifying under Section 401(k) of the Code that is sponsored by the Company for the benefit of its employees.

**“Account”**: A payroll deduction account maintained in the Participant’s name on the books of the Company.

**“Administrator”**: The Compensation Committee of the Board and its delegates, except that the Compensation Committee may delegate its authority under the Plan to a sub-committee comprised of one or more of its members, to members of the Board, or to officers or employees of the Company to the extent permitted by applicable law. In each case, references herein to the Administrator refer, as applicable, to such persons or groups so delegated to the extent of such delegation.

**“Board”**: The Board of Directors of the Company.

**“Code”**: The U.S. Internal Revenue Code of 1986 as from time to time amended and in effect, or any successor statute as from time to time in effect.

**“Company”**: Akebia Therapeutics, Inc.

**“Designated Subsidiary”**: A Subsidiary of the Company that has been designated by the Board or the Compensation Committee of the Board from time to time as eligible to participate in the Plan as set forth on Exhibit B to the Plan.

**“Effective Date”**: The date set forth in Section 23 of the Plan.

**“Eligible Employee”**: Any Employee who meets the eligibility requirements set forth in Section 4 of the Plan.

**“Employee”**: Any person who is employed by the Company or a Designated Subsidiary. For the avoidance of doubt, independent consultants and independent contractors are not “Employees.”

**“Exercise Date”**: The date set forth in Section 5 of the Plan or otherwise designated by the Administrator with respect to a particular Option Period on which a Participant will be deemed to have exercised the Option granted to him or her for such Option Period.

**“Fair Market Value”:**

(a) If the Stock is readily traded on an established national exchange or trading system (including the NASDAQ Global Market), the closing price of a share of Stock as reported by the principal exchange on which such Stock is traded; *provided, however*, that if such day is not a trading day, Fair Market Value will mean the reported closing price of a share of Stock for the immediately preceding day that is a trading day.

(b) If the Stock is not traded on an established national exchange or trading system, the average of the bid and ask prices for shares Stock where the bid and ask prices are quoted.

(c) If the Stock cannot be valued pursuant to clauses (a) or (b), the value as determined in good faith by the Board in its sole discretion.

**“Maximum Share Limit”:** The meaning set forth in Section 10 of the Plan.

**“Option”:** An option granted pursuant to the Plan entitling the holder to acquire shares of Stock upon payment of the Purchase Price per share of Stock.

**“Option Period”:** An offering period established in accordance with Section 5 of the Plan.

**“Parent”:** A “parent corporation” as defined in Section 424(e) of the Code.

**“Participant”:** An Eligible Employee who elects to enroll in the Plan.

**“Plan”:** The Akebia Therapeutics, Inc. 2014 Employee Stock Purchase Plan, as from time to time amended and in effect.

**“Purchase Price”:** The price per share of Stock with respect to an Option Period determined in accordance with Section 9 of the Plan.

**“Section 423”:** Section 423 of the Code and the regulations thereunder.

**“Stock”:** Common stock of the Company, par value \$0.001 per share.

**“Subsidiary”:** A “subsidiary corporation” as defined in Section 424(f) of the Code.

**EXHIBIT B**  
**Designated Subsidiaries**

Designated Subsidiaries as of the date of adoption of the Plan by the Board are listed below:

**AKEBIA THERAPEUTICS, INC.**  
**CASH INCENTIVE PLAN**

This Cash Incentive Plan (the “Plan”) has been established to advance the interests of Akebia Therapeutics, Inc. (the “Company”) by providing for the grant of Cash Incentive Awards to eligible employees of the Company and its subsidiaries, including Cash Incentive Awards intended to qualify for the performance-based compensation exemption (“Exempt Cash Incentive Awards”) under Section 162(m) of the Internal Revenue Code of 1986, as amended (the “Code”) (Section 162(m) of the Code, together with the regulations thereunder, “Section 162(m)”), to the extent applicable.

**I. ADMINISTRATION**

The Plan will be administered by the Committee and its delegates (the Committee and its delegates, to the extent of such delegation, are referred to herein as the “Administrator”); *provided*, that all determinations and other actions of the Administrator required by the performance-based compensation provisions of Section 162(m) to be made or taken by a “compensation committee” (as defined in Section 162(m)) will be made or taken hereunder directly by the Committee, and all references to the Administrator herein are to be construed accordingly. For purposes of the Plan, “Committee” means the Compensation Committee of the Board of Directors of the Company, except that if any member of the Compensation Committee is not an “outside director” (as defined in Section 162(m)), “Committee” means a subcommittee of the Compensation Committee consisting solely of those Compensation Committee members who are “outside directors” as so defined.

The Administrator has the authority to interpret the Plan and Cash Incentive Awards, to determine eligibility for Cash Incentive Awards, to determine the terms of and the conditions applicable to any Cash Incentive Award, and generally to do all things necessary to administer the Plan. Any interpretation or decision by the Administrator with respect to the Plan or any Cash Incentive Award will be final and conclusive as to all parties.

**II. ELIGIBILITY; PARTICIPANTS**

Executive officers and other key employees of the Company and its subsidiaries shall be eligible to participate in the Plan. The Committee will select, from among those eligible, the persons who will from time to time participate in the Plan (each, a “Participant”). Participation with respect to one Cash Incentive Award under the Plan will not entitle an individual to participate with respect to a subsequent Cash Incentive Award or Cash Incentive Awards, if any.

**III. GRANT OF AWARDS**

The term “Cash Incentive Award” as used in the Plan means an award opportunity that is granted to a Participant with respect to a specified performance period (consisting of the Company’s fiscal year or such other period as the Administrator may determine, each a “Performance Period”). A Participant who is granted a Cash Incentive Award will be entitled to a payment, if any, under the Cash Incentive Award only if all conditions to payment have been satisfied in accordance with the Plan and the terms of the Cash Incentive Award. By accepting

(or, under such rules as the Committee may prescribe, being deemed to have accepted) a Cash Incentive Award, the Participant agrees (or will be deemed to agree) to the terms of the Cash Incentive Award and the Plan. For each Cash Incentive Award, the Administrator shall establish the following:

- (a) the Performance Criteria (as defined in Section IV below) applicable to the Cash Incentive Award;
- (b) the amount or amounts that will be payable (subject to adjustment in accordance with Section V) if the Performance Criteria are achieved; and
- (c) such other terms and conditions as the Administrator deems appropriate, subject in each case to the terms of the Plan.

For Exempt Cash Incentive Awards, (i) such terms shall be established by the Committee not later than (A) the ninetieth (90th) day after the beginning of the Performance Period, in the case of a Performance Period of 360 days or longer, or (B) the end of the period constituting the first quarter of the Performance Period, in the case of a Performance Period of less than 360 days, and (ii) once the Committee has established the terms of such Cash Incentive Award in accordance with the foregoing, it shall not thereafter adjust such terms, except to reduce payments, if any, under the Cash Incentive Award in accordance with Section V or as otherwise permitted in accordance with the requirements of Section 162(m).

#### **IV. PERFORMANCE CRITERIA**

As used in the Plan, "Performance Criteria" means specified criteria, other than the mere continuation of employment or the mere passage of time, the satisfaction of which is a condition for the vesting, payment or full enjoyment of a Cash Incentive Award. A Performance Criterion and any targets with respect thereto determined by the Committee need not be based upon an increase, a positive or improved result or avoidance of loss and may be applied to a Participant or Participants on an individual basis, a business unit or division, or the Company as a whole. For Exempt Cash Incentive Awards, a Performance Criterion will mean an objectively determinable measure or objectively determinable measures of performance relating to any or any combination of the following (measured either absolutely or by reference to an index or indices and determined either on a consolidated basis or, as the context permits, on a divisional, subsidiary, line of business, project or geographical basis or in combinations thereof): sales; revenues; assets; expenses; earnings before or after deduction for all or any portion of interest, taxes, depreciation, amortization or equity expense, whether or not on a continuing operations or an aggregate or per share basis; return on equity, investment, capital, capital employed or assets; one or more operating ratios; operating income or profit, including on an after-tax basis; net income; borrowing levels, leverage ratios or credit rating; market share; capital expenditures; cash flow; stock price; stockholder return; sales of particular products or services; customer acquisition or retention; acquisitions and divestitures (in whole or in part); joint ventures, strategic alliances, licenses or collaborations; spin-offs, split-ups and the like; reorganizations; recapitalizations, restructurings, financings (issuance of debt or equity) or refinancings; manufacturing or process development; or achievement of clinical trial or research objectives, regulatory or other filings or approvals or other product development milestones. To the extent consistent with the requirements of Section 162(m), the Committee may establish that, in the case of any Exempt Cash Incentive Award, one or more of the Performance Criteria applicable to



such Cash Incentive Award will be adjusted in an objectively determinable manner to reflect events (for example, the impact of charges for restructurings, discontinued operations, mergers, acquisitions, extraordinary items, and other unusual or non-recurring items, and the cumulative effects of tax or accounting changes, each as defined by U.S. generally accepted accounting principles) occurring during the Performance Period that affect the applicable Performance Criterion or Criteria.

#### **V. CERTIFICATION OF PERFORMANCE; AMOUNT PAYABLE UNDER AWARDS**

As soon as practicable after the close of a Performance Period, the Administrator will determine whether and to what extent, if at all, the Performance Criterion or Criteria applicable to each Cash Incentive Award granted for the Performance Period have been satisfied and, in the case of Exempt Cash Incentive Awards, will take such steps as it determines to be sufficient to satisfy the certification requirement under Section 162(m) as to such performance results. The Administrator shall then determine the actual payment, if any, under each Cash Incentive Award. No amount may be paid under any Exempt Cash Incentive Award unless such certification requirement has been satisfied as set forth above, except as provided by the Administrator consistent with the requirements of Section 162(m). The Administrator may, in its sole and absolute discretion and with or without specifying its reasons for doing so, after determining the amount that would otherwise be payable under any Cash Incentive Award for a Performance Period, reduce (including to zero) the actual payment, if any, to be made under such Cash Incentive Award or, in the case of Cash Incentive Awards other than Exempt Cash Incentive Awards, otherwise adjust the amount payable under such Cash Incentive Award. The Administrator may exercise the discretion described in the immediately preceding sentence either in individual cases or in ways that affect more than one Participant. The actual payment under an Exempt Cash Incentive Award may be less than (but in no event more than) the amount indicated by the certified level of achievement under the Cash Incentive Award. The actual payment under a Cash Incentive Award other than an Exempt Cash Incentive Award may be more or less than the amount indicated by the level of achievement under the Cash Incentive Award. In each case, the Administrator's discretionary determination, which may affect different Cash Incentive Awards differently, will be binding on all parties.

#### **VI. PAYMENT UNDER AWARDS**

Except as otherwise determined by the Administrator or as otherwise provided in this Section VI, all payments under the Plan will be made, if at all, not later than March 15<sup>th</sup> of the calendar year following the calendar year in which the Performance Period ends; provided, that the Administrator may authorize elective deferrals of any Cash Incentive Award payments in accordance with the deferral rules of Section 409A of the Code and the regulations thereunder ("Section 409A"). The Administrator may, but need not, provide that a Cash Incentive Award payment will not be made unless the Participant has remained employed with the Company and its subsidiaries through the date of payment. Any deferrals with respect to an Exempt Cash Incentive Award will be subject to adjustment for notional interest or other notional earnings on a basis, determined by the Administrator, that is consistent with qualification of the Cash Incentive Award as exempt performance-based compensation under Section 162(m). Cash Incentive Awards under the Plan are intended either to qualify for exemption from, or to comply with the requirements of, Section 409A.

## **VII. PAYMENT LIMITS**

The maximum amount payable to any person in any fiscal year of the Company under Exempt Cash Incentive Awards will be \$2,000,000, which limitation, with respect to any such Cash Incentive Awards for which payment is deferred in accordance with Section VI above, shall be applied without regard to such deferral.

## **VIII. TAX WITHHOLDING; LIMITATION ON LIABILITY**

All payments under the Plan will be subject to reduction for applicable tax and other legally or contractually required withholdings.

Neither the Company nor any affiliate, nor the Administrator, nor any person acting on behalf of the Company, any affiliate, or the Administrator, will be liable for any adverse tax or other consequences to any Participant or to the estate or beneficiary of any Participant or to any other holder of a Cash Incentive Award that may arise or otherwise be asserted with respect to a Cash Incentive Award, including, but not limited to, by reason of the application of Section X below or any acceleration of income or any additional tax (including any interest and penalties) asserted by reason of the failure of a Cash Incentive Award to satisfy the requirements of Section 409A or by reason of Section 4999 of the Code.

## **IX. AMENDMENT AND TERMINATION**

The Committee may amend the Plan at any time and from time to time; provided, however, that, with respect to Exempt Cash Incentive Awards, no amendment for which Section 162(m) would require shareholder approval in order to preserve the eligibility of such Cash Incentive Awards as exempt performance-based compensation shall be effective unless approved by the shareholders of the Company in a manner consistent with the requirements of Section 162(m). The Committee may at any time terminate the Plan.

## **X. MISCELLANEOUS**

Cash Incentive Awards held by a Participant are subject to forfeiture, termination and rescission, and a Participant will be obligated to return to the Company payments received with respect to Cash Incentive Awards, in each case (a) to the extent provided by the Administrator in connection with (i) a breach by the Participant of a Cash Incentive Award agreement or the Plan, or any non-competition, non-solicitation, confidentiality or similar covenant or agreement with the Company or any of its affiliates or (ii) an overpayment to the Participant of incentive compensation due to inaccurate financial data, (b) in accordance with any applicable Company clawback or recoupment policy, as such policy may be amended and in effect from time to time, or (c) as otherwise required by law or applicable stock exchange listing standards, including, without limitation, Section 10D of the Securities Exchange Act of 1934, as amended. Each Participant, by accepting a Cash Incentive Award pursuant to the Plan, agrees to return the full amount required under this Section X at such time and in such manner as the Administrator shall determine in its sole discretion.

No person shall have any claim or right to be granted a Cash Incentive Award, nor shall the selection for participation in the Plan for any Performance Period be construed as giving a Participant the right to be retained in the employ or service of the Company or its affiliates for that Performance Period or for any other period. The loss of a Cash Incentive Award will not constitute an element of damages in the event of termination of employment for any reason, even if the termination is in violation of an obligation of the Company or any affiliate to the Participant.

In the case of any Exempt Cash Incentive Award, the Plan and such Cash Incentive Award will be construed and administered to the maximum extent permitted by law in a manner consistent with qualifying the Cash Incentive Award for the exemption for performance-based compensation under Section 162(m), notwithstanding anything to the contrary in the Plan. Cash Incentive Awards will not be required to comply with the provisions of the Plan applicable to Exempt Cash Incentive Awards (including, without limitation, the composition of the Committee as set forth in Section I above) if and to the extent they are eligible (as determined by the Committee) for exemption from such limitations by reason of the transition relief set forth in Treas. Regs. § 1.162-27(f).

The Plan shall be effective upon adoption of the Plan by the Board of Directors of the Company (the "Effective Date") and shall supersede and replace the Company's annual cash bonus program with respect to Cash Incentive Awards granted to eligible executive officers and employees after the Effective Date.

**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT  
REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

**MASTER SERVICES AGREEMENT**

This Master Services Agreement (“Agreement”) is made and entered into effective as of October 15, 2013 (the “Effective Date”), by and between Evonik Corporation (“Evonik”) with a principal place of business of 299 Jefferson Road, Parsippany, New Jersey, 07054 and Akebia Therapeutics, Inc. (“Customer”) with a principal place of business of 245 First Street, Suite 1100, Cambridge, MA 02142. Customer and Evonik are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”

**Recitals:**

A. Evonik is, among others, engaged in the business of supplying specialized development, formulation and manufacturing services of active pharmaceutical ingredients for the pharmaceutical industry and related industries and has considerable skills, expertise and know how in that field;

B. Customer is a biopharmaceutical company focused on the development of small molecules for the treatment of anemia, including the product candidate AKB-6548; and

C. Customer wishes to retain Evonik to perform certain services for Customer, including the development of AKB-6548, and production of drug substance for use in the Phase III clinical trial of AKB-6548 and Evonik wishes to provide such services, in each case subject to the terms and conditions set forth in this Agreement and each Proposal executed by the Parties pursuant to this Agreement.

**Agreement:**

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained, and intending to be legally bound hereby, the Parties hereby agree as follows:

**1. Definitions**

**1.1 Certain Definitions.** As used in this Agreement, the following terms shall have the meanings set forth below when capitalized:

(a) “Affiliate(s)” means, with respect to a Party, any other person, corporation, association or other entity that directly or indirectly owns, is owned by, or is under common ownership of such Party, either now or at any time during the term of this Agreement. The terms “owns,” “owned,” or “ownership” mean the direct or indirect possession of more than fifty percent (50%) of the voting securities of, or income interest or comparable equity in, such entity.

(b) “Background IP” has the meaning set forth in Section 4.1.

(c) “Clinical Product” means units of Product (defined herein) which are to be used in Phase III clinical trials.

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(d) "Invention" means any and all inventions, trade secrets, discoveries, developments, know-how, methods, techniques, formulae, processes and compositions of matter, whether or not patentable, conceived, reduced to practice, created, or otherwise resulting from or derived from or directly relating to Customer's and/or Evonik's performance under this Agreement.

(e) "Product" means the substance referred to by Customer as of the Effective Date by the designation AKB-6548, which is a HIF2 stabilizer (HIF-PH inhibitor).

(f) "Project(s)" shall mean the services to be rendered to Customer by Evonik pursuant to a Proposal and the related Work Product. Each new Project will require a new Proposal and each new Proposal shall be incorporated by reference into this Agreement and all services provided under a Proposal shall be subject to the terms and conditions of this Agreement. The first six (6) Projects hereunder are set forth in the Proposals attached hereto as Attachments B-1 through B-6, respectively, all of which are made a part of this Agreement as of the Effective Date.

(g) "Proposal" shall mean a description of a set of services and products to be provided by Evonik to Customer under this Agreement, as mutually agreed in writing, executed and delivered by the Parties from time to time. A template for a Proposal is attached as Attachment A.

(h) "Work Product" shall mean and include all work product and deliverables created, developed, compiled or otherwise generated by Evonik in the course of rendering services for a Project, including any data, documentation, Product and/or Clinical Product.

**1.2 Additional Defined Terms.** As used in this Agreement, additional defined terms shall have the meaning set forth in the specific section or paragraph where identified when capitalized.

**1.3 Interpretation.** Whenever the context requires, any pronoun shall include the corresponding masculine, feminine and neuter forms. The words "include," "includes" and "including" shall be deemed to be followed by the phrase "without limitation." Except as specifically otherwise provided in this Agreement, a reference to an Article, Section or Exhibit is a reference to an Article, Section or Exhibit of this Agreement, and the terms "hereof," "herein," and other like terms refer to this Agreement as a whole, including attachments. The term "or" is used in its inclusive sense ("and/or"). The term "Dollars" and symbol "\$" shall mean United States Dollars.

## **2. Services**

**2.1 Scope of Services; Professional Standards; Use of Subcontractors.** Evonik shall render services in connection with each Project and create, develop and deliver the required Work Product for each Project to Customer, all in accordance with the relevant Proposal, subject to the terms and conditions of this Agreement. Such services shall be provided by Evonik in a timely manner using high professional standards, and in all cases in compliance with all laws and regulations which are applicable to Evonik's performance of services under the Agreement,

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including cGMP. In performing such services, Evonik shall use only (a) personnel who are trained, qualified and experienced to perform such services and (b) unless otherwise approved in advance by Customer, employees of Evonik or Evonik Affiliates who have obligations of confidentiality and to assign all right, title and interest in all Inventions and Work Product to Evonik. If Evonik uses employees of any of its Affiliates to provide any of the services under this Agreement, then Evonik will be responsible for the acts and omissions of such employees as if they were Evonik in this Agreement.

**2.2 Change Order Process.** If at any time during the term of this Agreement Customer desires to make modifications to a Proposal, Customer shall provide a written description of the proposed modification(s) to Evonik (a "Change Request"). Within five (5) business days after its receipt of such Change Request, Evonik shall submit a change order proposal (the "Change Order") that includes any additional fees or charges and any adjustments to the completion dates or Proposal timetable resulting from the proposed Change Request. Once the Change Order is executed by both Parties, such Change Order shall become a part of the applicable Proposal and Project under this Agreement. The Parties recognize that the Proposal is necessarily a general description of the work to be done for a Project and that more specific direction on such work to be performed may need to be provided by Customer from time to time. More specific directions shall not be deemed a Change Request for which any additional fees or charges are due unless such direction is outside the scope of the general work described by the Proposal.

**2.3 Title / Risk of Loss; Shipping.** Title and risk of loss of all Work Product to be delivered to Customer shall pass to Customer upon receipt by Customer. Unless otherwise mutually agreed in writing, all Work Product not hand delivered from Evonik to Customer shall be shipped DDP (Incoterms 2010) to an address specified by Customer.

**2.4 Reports.** Evonik will prepare and submit progress reports for each Project or portion thereof if and as described in the Proposal or as otherwise mutually agreed. Within thirty (30) days after completion of a Project, Evonik will submit to Customer a final report that (i) summarizes in reasonable detail all activities performed, data generated, and Inventions solely by Evonik and (ii) contains any other information specified in the Proposal to be included or as otherwise mutually agreed.

**2.5 Project Records.** Evonik will prepare, record and maintain, and shall require all employees and approved subcontractors involved in a Project to prepare, record and maintain, accurate records and data relating to the progress and status of its activities under each Project, including all records relating to any development or manufacturing of any Product or Clinical Product. From time-to-time throughout the Term upon reasonable advance notice by Customer, Evonik will disclose to or permit direct access to, during regular business hours, Customer or its designated representatives all such records and data for the purpose of reviewing and copying, if so desired by Customer.

**2.6 Quality Agreement.** Upon the Effective Date the parties have simultaneously executed a Quality Agreement which describes the relationship of the Parties hereunder and the responsibilities of each party regarding quality systems practices and activities concerning the

Projects. This Agreement is intended to govern all provisions regarding the purchase and sale of all Product and Clinical Product between the Parties and all terms, obligations, responsibility, and liability regarding same. The aforementioned Quality Agreement is intended to address the quality of the Products and Clinical Products and each party's responsibilities regarding quality systems practices and activities concerning the Product. All of the terms of the Quality Agreement shall apply to each Project, except to the extent otherwise specified in its Proposal. In the event of a conflict between this Agreement and the Quality Agreement, this Agreement shall govern except to the extent the conflict is regarding the quality of the Product to be supplied hereunder, in which case the Quality Agreement shall govern.

### 3. Fees and Expenses

#### 3.1 Fees.

(a) The estimated budget for the services conducted for each Proposal will be included in an executed Proposal (the "Estimated Budget"). Evonik shall not bill Customer for amounts greater than the Estimated Budget without the express written consent of Customer. Customer shall pay Evonik as outlined in the Proposal associated with a Project. Furthermore, the Parties may decide to amend or add additional services through an amended Proposal pursuant to Sections 2.2 of this Agreement. In such cases the Parties may amend or extend the Estimated Budget and agree on specific fee arrangements as it relates to the amended Proposal, which may be set forth in the amended Proposal.

(b) Evonik must complete each Project, including delivery of all Work Product to Customer, within its Estimated Budget (as amended by any Change Orders), unless impossible due to circumstances that were unforeseen and unforeseeable at the time of adoption of the corresponding Proposal (or any Change Order thereto). Except as otherwise specified in a Proposal, Evonik is responsible for the procurement and supply of all active pharmaceutical ingredients, other raw materials, supplies, packaging, and other materials, as well as for providing all labor necessary for the performance of its portion of the activities within each Project.

**3.2 Payment.** Evonik shall send invoices to the address of Customer in the Notice provision below, "Attention: Accounts Payable", at the time(s) specified in the Proposal for a Project. Customer shall pay all invoices within thirty (30) days of the date of invoice if properly invoiced. Further, if at any time, Customer fails to pay an invoice within thirty (30) days after Evonik's notice to Customer that payment is overdue, Evonik may in its own discretion, refuse to provide services for the subject Project, including delivery of any Work Product, until all invoices overdue for the Project are paid and/or the Parties agree to change the payments terms. If Customer disputes one portion of an invoice but not another, then Customer may pay only the undisputed portion until such time as the dispute is resolved. No portion of an unpaid invoice that is the subject of a reasonable dispute by Customer may be deemed late for purposes hereunder unless Customer does not pay the amount properly due promptly after the dispute is resolved.

#### 4. Ownership of Inventions; Intellectual Property Rights

**4.1 Background Intellectual Property.** The Parties acknowledge that the (a) intellectual property owned by or licensed to Evonik or Customer existing prior to the Effective Date including, but not limited to, inventions, trade secrets, discoveries, developments, know-how, methods, techniques, formulae, processes, compositions of matter, technical information and confidential information existing prior to the Effective Date, and (b) intellectual property that is conceived, reduced to practice, created, or otherwise entirely results from work performed outside of either Party's performance under this Agreement (together, the "Background IP"), are and will remain the separate property of Evonik or Customer. Except as expressly permitted under this Agreement, neither Party shall have any claims to or rights in or to such separate Background IP of the other Party.

**4.2 Disclosure.** Promptly after the conception, reduction to practice, creation, discovery or development of an Invention by Evonik, Evonik must notify Customer in writing of such Invention and must provide Customer with full and complete information so as to enable Customer to make a patent application or to seek other intellectual property protection for that Invention. Until such time as mutually agreed in writing, Evonik must maintain in strict confidence all details of any Invention, whether it is to be patented or retained by Customer as know-how and/or trade secret.

**4.3 Inventorship; Authorship.** Inventorship for all Inventions, whether or not patentable, shall be determined in accordance with U.S. patent laws. Authorship of all works of authorship created in the course of a Project by either Party shall be determined in accordance with U.S. copyright laws.

**4.4 Ownership of Inventions.** [\*\*\*] Evonik shall cooperate, and cause its employees and permitted contractors to cooperate, with Customer as reasonably requested from time to time to further document and record Customer's sole ownership of all such Inventions.

**4.5 Ownership of Work Product.** As between the Parties, all Work Product shall be the sole property of the Customer. The Parties intend that all Work Product that is protectable by copyright is "work made for hire," as that term is defined in the United States Copyright Act for which Customer is the owner and author. To the extent that any such Work Product cannot by law be "work made for hire", then immediately upon existence and without further action by either Party, Evonik hereby assigns to Customer all of Evonik's rights, title and interest therein. Evonik shall cooperate, and cause its employees and permitted contractors to cooperate, with Customer as reasonably requested from time to time to further document and record Customer's sole ownership of all Work Product.

**4.6 Use of Evonik Background IP.** In the event that any Invention or Work Product incorporates, otherwise relies upon, or is derived from any Evonik Background IP as a result of any the Services provided by Evonik in connection with a Project, Evonik hereby grants to Customer a non-exclusive, irrevocable, non-terminable, transferable, [\*\*\*], worldwide license, including the right to sublicense, under all of Evonik's rights in such Evonik Background IP as reasonably required to exploit the Product, Clinical Product, Inventions, and Work Product.



**4.7 Intellectual Property Rights Prosecution, Maintenance and Enforcement.**

(a) Evonik shall have the sole right (but not the obligation), at its expense, to prepare, file, prosecute and maintain patent applications or patents or other forms of protection for Evonik Background IP. Evonik shall have the sole right to enforce all intellectual property rights in the Evonik Background IP.

(b) Customer shall have the sole right (but not the obligation), at its expense, to prepare, file, prosecute and maintain patent applications or patents or other forms of protection for Inventions and Customer Background IP. Customer shall have the sole right to enforce all intellectual property rights in the Inventions, Work Product and Customer Background IP.

**4.8 License.** Customer hereby grants to Evonik a license under the Customer Background IP, Inventions and Work Product, and all intellectual property rights therein, as strictly necessary for Evonik to fulfill its obligations under this Agreement. Except as provided in the preceding sentence, Customer reserves all right, title and interest in the Customer Background IP, Inventions and Work Product, and all intellectual property rights therein, and does not grant any right, title or interest therein to Evonik by implication, estoppel or otherwise. Evonik shall not disclose, use or otherwise exploit any of the foregoing for any other purpose or otherwise not strictly permitted by this Agreement.

**5. Representations**

**5.1 Evonik Representations.** Evonik hereby represents to Customer as of the date hereof that:

(a) Evonik has all requisite organizational power and authority to enter into this Agreement and to carry out the transactions contemplated hereby and thereby;

(b) the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite organizational action on the part of Evonik;

(c) this Agreement has been or will be duly executed and delivered by Evonik and is a valid and binding obligation of Evonik, enforceable against it in accordance with its terms;

(d) Evonik's execution and delivery of this Agreement does not and will not violate or constitute a breach of any of its contractual obligations with third parties;

(e) to the best of Evonik's knowledge, it does not own any Background IP that is related to the Product; and

(f) Evonik has access to all necessary employees, equipment, property, materials or other things necessary to completely fulfill each Project in a timely manner in accordance with its corresponding Estimated Budget and the Proposal, and can perform its obligations under this Agreement in compliance with all specifically applicable laws and regulations which are applicable to Evonik's performance of services under this Agreement.

**5.2 Customer Representations.** Customer hereby represents to Evonik as of the date hereof that:

(a) Customer has all requisite organizational power and authority to enter into this Agreement and to carry out the transactions contemplated hereby and thereby;

(b) the execution, delivery and performance of this Agreement and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite organizational action on the part of Customer;

(c) this Agreement has been or will be duly executed and delivered by Customer and is a valid and binding obligation of Customer, enforceable against it in accordance with its terms; and

(d) Customer's execution and delivery of this Agreement does not and will not violate or constitute a breach of any of its contractual obligations with third parties.

## **6. Term and Termination**

**6.1 Term.** This Agreement shall commence on the Effective Date and shall continue for the longer of (a) three (3) years and (b) termination of the last Project which is subject to this Agreement, unless terminated sooner pursuant to Sections 6.2 – 6.5 hereof. The period from the Effective Date until termination is the "Term."

**6.2 Termination by Either Party.** At any time when a Proposal is not active, either Party may terminate this Agreement at any time, for any reason or for no reason, by giving written notice of termination to the other Party not less than thirty (30) days prior to the effective date of such termination. Either Party may also terminate this Agreement for a Force Majeure as provided in Section 11.1.

**6.3 Termination by Customer.** Customer may terminate this Agreement or any Project upon thirty (30) days written notice to Evonik.

**6.4 Termination for Breach.** In the event of a material breach of this Agreement by either Party that remains uncured for more than sixty (60) days following such Party's receipt of written notice thereof from the non-breaching Party specifying in reasonable detail the nature of such breach, the non-breaching Party may terminate this Agreement. Except as expressly limited by this Agreement, termination of this Agreement shall be without prejudice to any other remedies that may be available to a Party due to breach by the other Party of this Agreement.

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REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

**6.5 Bankruptcy and Insolvency.** If either Party shall liquidate or dissolve, or shall be declared bankrupt according to law, or shall make an assignment of its property for the benefit of creditors, or shall file any petition with a court of competent jurisdiction for reorganization under any bankruptcy or insolvency laws, or such petition shall be filed against it and not dismissed within ninety (90) days, or shall have a receiver appointed for a substantial part of its assets who is not discharged within ninety (90) days of his appointment, the other Party shall have the right to terminate this Agreement effective upon the giving of written notice thereof to such Party.

**6.6 Survival of Certain Obligations.**

(a) Upon termination of this Agreement by Customer pursuant to Section 6.3 or by Evonik pursuant to Section 6.4 or 6.5, Evonik will be paid any amounts owed to Evonik for work that has been performed through the effective date of termination, including any non-cancelable third party costs reasonably incurred by Evonik in connection with the Project if such costs were explicitly part of the Estimated Budget or otherwise were pre-approved in writing by Customer.

(b) Upon termination of this Agreement for any reason, (i) any obligations accruing before the effective date of termination shall survive termination in accordance with their terms, and (ii) within thirty (30) days after termination, Evonik shall provide to Customer all Work Product then in existence and not previously provided to Customer.

(c) Upon termination of this Agreement for any reason other than by Evonik for material breach of Customer under Section 6.4, unless otherwise directed by Customer, Evonik shall complete the production of any Products for which the production process has started as of the time to termination, and Customer's payment obligations with respect to such Products shall survive termination in accordance with their terms.

(d) Notwithstanding anything else written in this Agreement, the rights and obligations of the Parties under Sections 4, 6.6, 7, 8 and 10 and any other provision expressly indicated to survive termination shall survive the termination of this Agreement for any reason in accordance with their terms.

**7. Warranties; Disclaimer.**

**7.1 Product/Clinical Product Warranty; Disclaimer.**

(a) EVONIK WARRANTS THAT FOR ANY PROJECT PURSUANT TO WHICH EVONIK IS TO SUPPLY PRODUCT OR CLINICAL PRODUCT TO CUSTOMER AND FOR WHICH THE PARTIES EXPLICITLY AS PART OF SUCH PROPOSAL AGREE TO A WRITTEN SET OF SPECIFICATIONS, EVONIK WARRANTS THAT UPON DELIVERY OF SUCH PRODUCT OR CLINICAL PRODUCT TO CUSTOMER AND FOR THE DURATION OF ANY POST-DELIVERY PERIOD SPECIFIED IN SUCH SPECIFICATIONS, SUCH PRODUCT OR CLINICAL PRODUCT SHALL MEET SUCH AGREED UPON SPECIFICATIONS. EVONIK FURTHER WARRANTS THAT ALL PRODUCTS AND CLINICAL PRODUCTS DELIVERED TO CUSTOMER SHALL HAVE BEEN MADE AND DELIVERED IN ACCORDANCE WITH CGMP AND ALL LAWS AND REGULATIONS APPLICABLE TO THE PERFORMANCE OF THE PROPOSALS UNDER THIS AGREEMENT.

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(b) THE EXPRESS WARRANTIES PROVIDED IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND EVONIK MAKES NO OTHER WARRANTY, INCLUDING, WITHOUT LIMITATION, THAT THE PRODUCTS AND CLINICAL PRODUCTS PROVIDED ARE MERCHANTABLE OR SATISFACTORY FOR ANY PARTICULAR PURPOSE. NO OTHER WARRANTY SHALL APPLY TO ANY OF THE PRODUCTS OR CLINICAL PRODUCTS PROVIDED HEREUNDER EXCEPT AS EXPRESSLY STATED HEREIN. FURTHERMORE, CUSTOMER SHALL NOT MAKE ANY REPRESENTATION OR WARRANTY ON BEHALF OF EVONIK.

**7.2 Customer Intellectual Property Warranty.** Customer represents to Evonik that, [\*\*\*], the manufacture of the Products by Evonik for Akebia upon the terms and conditions of this Agreement, including the specifications and other conditions set forth in the applicable Proposal, will not infringe upon any U.S. patent of any third party, and Akebia's provision of the information provided to Evonik in connection with this Agreement does not constitute misappropriation of trade secrets or copyright infringement of the trade secrets or copyrights of any third party.

**7.3 Weight of Delivered Products.** Evonik warrants that Evonik's measurements shown on the packaging slip accompanying each delivery of Product or Clinical Product will accurately reflect the contents. Such quantity measurements reported by weight on such packaging slip shall be deemed to be correct unless Customer notifies Evonik in writing of a shortage within ten (10) business days after the date of delivery. In the event of a shortage, Customer will remain liable for payment for the Product delivered and Evonik shall promptly deliver to Customer an amount of Product necessary to eliminate such shortage.

## **8. Indemnification; Limitation of Liability**

**8.1 Indemnification by Customer.** Subject to Sections 8.2 and 8.3 as applicable, Customer shall defend, indemnify and hold harmless Evonik, its Affiliates, and its and their respective directors, officers, employees, principals, agents and assigns ("Evonik Personnel") from and against any and all losses, penalties, actions, damages, liabilities, costs and expenses incident thereto (including reasonable legal counsel fees and expenses) (the "Losses") which any Evonik Personnel may hereafter incur, become responsible for or pay out relating to, based upon, arising out of or in connection with any third party claim to the extent based upon (a) Customer's breach of any of its representations, warranties, covenants or obligations under this Agreement; (b) any infringement or misappropriation of the intellectual property rights of any third party relating to the Evonik Personnel's use in compliance with the terms of this Agreement of any of the Customer Background IP provided by Customer to Evonik in connection with the Project or Evonik's performance of a Proposal, including its manufacture of the Products according to the formulation provided by Customer; (c) any use of the Work Product after delivery to Customer in a manner inconsistent with the use for which such Work Product was developed; (d) the negligence or misconduct or omission of any Customer Personnel in the performance of the

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Project; or (e) the development, manufacture, use, sale or other disposition of any Work Product or product incorporating the Work Product after delivery to Customer; in each case, except to the extent that any of the foregoing is the subject of Evonik's indemnity obligation to Customer under Section 8.2.

**8.2 Indemnification by Evonik.** Subject to Sections 8.1 and 8.3 as applicable, Evonik shall defend, indemnify and hold harmless Customer, its Affiliates, and its and their respective directors, officers, employees, principals, agents and assigns ("Customer Personnel") from and against any and all Losses which any Customer Personnel may hereafter incur, become responsible for or pay out relating to, based upon, arising out of or in connection with any third party claim to the extent based upon (a) [\*\*\*]; (b) any infringement or misappropriation of the intellectual property rights of any third party relating to any acts of Evonik Personnel in (i) utilizing Customer Background IP in a manner inconsistent with the terms of this Agreement or (ii) solely related to the use of Evonik Background IP in the performance of a Project or Proposal; (c) [\*\*\*] or (d) the acts or omissions of any subcontractors of Evonik, including its Affiliates or other Evonik Personnel, that would, if by Evonik, be deemed a breach of any of its representations, warranties, covenants or obligations under this Agreement.

**8.3 Indemnification Procedures.**

(a) Each of the Evonik Indemnitees and Customer Indemnitees are an "Indemnitee" for the purpose of this Section 8, and the Party that is obligated to indemnify the Indemnitee under Section 8.1 or Section 8.2 shall be the "Indemnifying Party."

(b) The Indemnitee shall notify the Indemnifying Party promptly of any claim, demand, action or other proceeding under Section 8.1 or Section 8.2 and shall reasonably cooperate with all reasonable requests of the Indemnifying Party with respect thereto.

(c) If any such claims or actions are made, the Indemnitee shall be defended at the Indemnifying Party's sole expense by counsel selected by Indemnifying Party and reasonably acceptable to the Indemnitee, *provided that* the Indemnitee may, at its own expense, also be represented by counsel of its own choosing. The Indemnifying Party shall have the sole right to control the defense of any such claim or action, subject to the terms of this Section 8.

(d) The Indemnifying Party may settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment (i) with prior written notice to the Indemnitee but without the consent of the Indemnitee where the only liability to the Indemnitee is the payment of money and the Indemnifying Party makes such payment, or (ii) in all other cases, only with the prior written consent of the Indemnitee, such consent not to be unreasonably withheld. The Indemnitee may not settle any such claim, demand, action or other proceeding or otherwise consent to an adverse judgment in any such action or other proceeding or make any admission as to liability or fault without the express written permission of the Indemnifying Party.

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**8.4 Limitation of Liability.** EXCEPT FOR BREACH OF SECTION 10, AS REQUIRED TO MEET AN INDEMNIFICATION OBLIGATION, OR IN THE EVENT OF AN INTENTIONAL AND WILFUL BREACH IN BAD FAITH OF ANY REPRESENTATION, WARRANTY, COVENANT OR AGREEMENT CONTAINED IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY UNDER THIS AGREEMENT FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR PUNITIVE DAMAGES, REGARDLESS OF WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHERWISE INCLUDING, BUT NOT LIMITED TO, LOSS OF PRODUCT, PROFITS OR REVENUES, DAMAGE OR LOSS FROM OPERATION OR NONOPERATION OF PLANT. EVONIK'S TOTAL LIABILITY UNDER THIS AGREEMENT FOR ANY AND ALL CLAIMS WHATSOEVER, INCLUDING ANY THIRD PARTY CLAIMS PURSUANT TO SECTION 8.2, SHALL NOT EXCEED, IN THE AGGREGATE [\*\*\*] BY CUSTOMER UNDER THIS AGREEMENT.

**9. Insurance.** Each Party shall, at its sole cost and expense, procure and maintain in full force during the entire Term of this Agreement the following types of insurance in the minimum amounts set forth below with insurance carriers having a rating of A as to financial strength by the latest edition of A. M. Best & Co:

- (a) Workers' Compensation insurance in accordance with the laws of the state(s) of operations covering all Customer's employees, subcontractors, or their employees who may be engaged directly or indirectly in any work hereunder and Employer's Liability Insurance coverage in the amount of \$1,000,000.00 (one million dollars) for its employees;
- (b) Comprehensive General Liability insurance including Customer's Completed Operations, covering bodily injuries and property damage with combined single limits of \$1,000,000.00 (one million dollars) each occurrence and \$2,000,000.00 (two million dollars) aggregate; and
- (c) Product Liability insurance, including clinical trial coverage, in the amount of \$5,000,000 (five million dollars) aggregate.

Upon request of a Party, the other Party shall furnish to the requesting Party a copy of the certificate of insurance evidencing such coverages referred herein. No policy provided hereunder shall be cancelled nor materially reduced without thirty (30) days' written notice to the other Party. All stated insurance policies, where applicable, will designate the other Party as additional insured, without qualifications or limitation, as its interest may appear.

**10. Confidentiality; Return/Destruction of Tangible Materials**

**10.1 Confidential Information.**

(a) Both Parties acknowledge that it may be necessary for each to disclose certain technical and proprietary information with respect to the Agreement to the other Party. For purposes of this Agreement, the term "Confidential Information" means all information which is disclosed by or on behalf of the Party that disclosed the information (the "Disclosing Party") to the Party that receives the information (the "Receiving Party") in writing or other tangible medium, including information relating to the matters which are the subject of this Agreement, the terms of this Agreement, and all other materials and information regarding the Disclosing Party's technology, know-how, products, markets, prototypes, business information and operations, or technical information; *provided, however*, that notwithstanding which Party first discloses any Inventions or Work Product to the other, all Inventions and Work Product are the Confidential Information of Customer for which Customer is the Disclosing Party and Evonik the Receiving Party and with respect to which clause (ii) below shall not apply. Confidential Information shall not include:

- (i) information, that at the time of disclosure, is in the public domain, or that thereafter enters the public domain, through no act or omission of the Receiving Party; or
- (ii) information that the Receiving Party or its Personnel can establish by reasonable proof was in their possession at the time of disclosure, or was subsequently; or
- (iii) information independently developed by Personnel of the Receiving Party who had no knowledge of that information as a disclosure from the Disclosing Party; or
- (iv) information that is hereafter lawfully received by the Receiving Party or its Personnel on a non-restricted basis from another source having rightful possession of such Confidential Information and the legal right to disclose it to the Receiving Party as documented by the Receiving Party's written records; or
- (v) information that the Disclosing Party or its Personnel agrees in writing to release from the obligations under this Section 10.

The burden of proving the applicability of any one or more of the above exceptions shall at all times be with the Receiving Party.

(b) An individual feature of Confidential Information shall not be deemed to be within any of the specified exceptions merely because it is embraced by more general information in such exception. In addition, any combination of features shall not be deemed to be within any of the specified exceptions merely because individual features are in such exception, but only if the combination itself and its principle of operation are in such exception.

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(c) Any disclosure of Confidential Information made by the Receiving Party in response to a valid order by a court or other governmental body or that is otherwise required by law (but only to the extent of such order or requirement), including a disclosure of this Agreement or the material terms thereof as required by the Securities and Exchange Commission, will not be deemed to be a violation of the Receiving Party's obligations under this Agreement if the Receiving Party follows the instructions of this Section 10. Under such circumstances, the Receiving Party agrees that it will (to the extent permitted by applicable law) use reasonable commercial efforts to provide the Disclosing Party with immediate notice of any disclosure to be made pursuant to such order or requirement and cooperate, at the expense of and with the efforts of the Disclosing Party, to obtain a protective order or other assurance of confidential treatment of the Confidential Information to be disclosed pursuant to such order or requirement. If, in the absence of a protective order, the Receiving Party is compelled as a matter of law to disclose the Confidential Information, the Receiving Party will disclose, without liability, only that part of the Confidential Information as is required by law to be disclosed and prior to such disclosure will, to the extent permitted by applicable law, advise and consult with the Disclosing Party as to such disclosure.

(d) During the term of this Agreement and through the period of non-disclosure and non-use below, the Receiving Party agrees that it will not (i) use Confidential Information of the Disclosing Party for any purpose except as set forth in the Proposal and in accordance with this Agreement, or (ii) disclose Confidential Information of the Disclosing Party to any third party without the advance written approval of the Disclosing Party, or (iii) disclose results under the Proposal that use or disclose the Confidential Information of the Disclosing Party without the advance written approval of the Disclosing Party. The Receiving Party's obligations of non-disclosure and non-use shall continue for a period of ten (10) years from the termination or expiration date of this Agreement.

(e) Notwithstanding the above, the Receiving Party may, in its sole discretion, disclose Confidential Information of the Disclosing Party to the Receiving Party's Personnel who require the same in the performance of their regular responsibilities, and then only to the extent required to perform the Project contemplated hereunder, who have been advised of the confidential nature of the Confidential Information and of the restrictions hereunder on its disclosure and use, and agree to maintain the same in confidence and not to use the same other than as herein. Further, to the extent that Confidential Information is disclosed to the Receiving Party or Receiving Party's Personnel by the Disclosing Party's Personnel, this Agreement shall also apply to such disclosures. The Parties to this Agreement shall assume full responsibility for its Personnel in this regard.

**10.2 Return/Destruction of Tangible Materials.**

Upon the Disclosing Party's request, the Receiving Party will return (and will cause all Personnel to return) all Confidential Information of the Disclosing Party in written or manifested in other tangible form to the Disclosing Party, and shall also deliver to it all copies, extracts, summaries, adaptations and drawings, whether provided by the Disclosing Party or created by the Receiving Party. The Receiving Party shall also deliver to the Disclosing Party any equipment, sample, product or material embodying, containing or based upon any of Disclosing



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Party's Confidential Information. Notwithstanding the above, (a) the Receiving Party may retain a record copy for the purpose of determining either Party's rights, obligations, and/or disclosures made under this Agreement, (b) Receiving Party shall not be required to destroy any computer files created during automatic system back-ups that are subsequently stored securely and not accessible to employees, except for the purpose of securing application of the Agreement, and (c) Customer may retain and continue to use all Confidential Information of Evonik as reasonably necessary for Customer to exploit the Products, Clinical Products, Inventions and Work Product in compliance with all applicable laws, *provided that*, all Confidential Information made and kept by Receiving Party shall continue to be governed by the terms of this Agreement.

**10.3 Existence of Agreement.**

Notwithstanding anything to the contrary herein, a Party may disclose the existence and terms of this Agreement: (A) in connection with filings required by securities and tax regulations and the rules and regulations of any securities exchanges upon which a Party's or its Affiliate's securities are traded, *provided, however*, that such Party shall use reasonable efforts to limit the dissemination of such information; (B) to a Party's actual and potential lenders, private investors, bankers, accountants, and lawyers who are subject to an obligation of confidentiality; and (C) to a Party's actual and bona fide potential assignees or transferees permitted in accordance with Section 11.3 subject to an obligation of confidentiality prohibiting further disclosure of the information.

**11. Miscellaneous**

**11.1 Force Majeure.** Neither Party shall be liable for delay or failure to perform its obligations hereunder due to any circumstances beyond its reasonable control, regardless whether such circumstances can be reasonably foreseen. Such circumstances include, but are not limited to acts of God, war (declared or undeclared), acts of terrorism (and related government actions), riot, political insurrection, rebellion, sabotage, revolution, acts, laws, regulations or orders of or expropriation by any government (whether de facto or de jure), acts of government prohibiting sanction the import or export of the product, rationing, equipment or production facilities, quarantine restrictions, fuel shortage, strike, lock-out or other labor troubles which interfere with the manufacture or transportation of the Product or with the supply of raw materials necessary for their production or fire, flood, explosion, earthquake, tornados or other natural events or disasters, national defense or security requirements and natural disasters ("Force Majeure"). If such Force Majeure occurs, the affected Party shall notify the other Party in writing as soon as practicable of the occurrence of said Force Majeure event, the nature of and expected duration of the Force Majeure event as well the effect the Force Majeure event will have on that Party's performance of this Agreement. The affected Party will be excused from performing its obligations hereunder only during the Force Majeure event and the affected shall not be liable to the other for damages by reason of any delay or suspension of performance resulting from the Force Majeure event; provided, however, that if either Party claims non-performance based upon Force Majeure for more than sixty (60) days or the other Party reasonably believes the Force Majeure event is likely to continue for more than sixty (60) days, then the other Party may terminate this Agreement by notice.

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**11.2 Parties Independent.** In making and performing this Agreement, the Parties are acting and shall act at all times as independent contractors and nothing contained in this Agreement shall be construed or implied to create an agency, partnership, or joint venture relationship between the Parties.

**11.3 Assignment; Successors and Assigns.** Neither Party may assign all or any part of this Agreement without the other Party's prior written consent, which shall not be unreasonably withheld. Notwithstanding the foregoing, either Party may assign this Agreement (1) to an Affiliate, including its parent company; or (2) in the event of a merger, acquisition or sale of substantially all of the assets of a Party or the portion of that Party's business responsible for performance of this Agreement. This Agreement shall inure to the benefit of and be binding upon the Parties and their successors and permitted assigns.

**11.4 Notices.** All notices, consents, claims, demands or other communications given under this Agreement shall only be sufficient if in writing and sent (1) by certified mail, return receipt requested, postage prepaid or (2) by a nationally recognized overnight courier service which provides a delivery receipt, to the Parties at the address set forth below or at such other address designated by either Party in writing. The date of giving such notice will be deemed to be three (3) days after such envelope was deposited with the U.S. Postal Service or courier service. The Post Office or courier service receipt showing the date of such deposit shall be prima facie evidence of such deposit date. Such communications must be sent to the respective Parties at the following addresses:

**For Evonik:**

Evonik Corporation  
299 Jefferson Road  
Parsippany, NJ 07054  
FAX: (973) 929-8160  
Attention: Business Head Custom Manufacturing North America

And

Evonik Corporation  
299 Jefferson Road  
Parsippany, New Jersey 07054  
FAX: (973) 541-8850  
Attention: General Counsel

**For Customer:**

Akebia Therapeutics, Inc.  
245 First Street, Suite 1100  
Cambridge, MA 02142  
FAX: 617-871-2099  
Attention: Chief Executive Officer

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With a copy to:

Akebia Therapeutics, Inc.  
245 First Street, Suite 1100  
Cambridge, MA 02142  
FAX: 617-871-2099  
Attention: General Counsel

**11.5 Remedies.** Each Party acknowledges that a breach of such Party's obligations in Sections 4 and 10 hereof may result in irreparable and continuing damage to the other Party for which there may be no adequate remedy at law; and each Party agrees that, in the event of any breach of the aforesaid agreements, the other Party and its successors and assigns may be entitled to injunctive relief and to such other and further relief as may be proper.

**11.6 Waiver of Breach.** The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect that Party's right at a later time to enforce the same. No waiver by any Party of the breach of any term or covenant contained in this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be, or construed as, a further or continuing waiver of any such breach, or a waiver of the breach of any other term or covenant contained in this Agreement.

**11.7 Headings; Construction.** Section headings contained in this Agreement are included for convenience only, and are not a part of the agreement between the Parties. The language used in this Agreement is the language chosen by the Parties to express their mutual intent. No rule of strict construction shall be applied against either Party.

**11.8 Invalid or Void Provisions.** In the event that individual provisions of this Agreement become wholly or partially invalid as evidenced by a ruling of a court of competent jurisdiction, the effectiveness of the remaining provisions shall not be affected, to the extent severable. The Parties undertake in good faith to replace an invalid provision by a valid one which most closely corresponds with the economic intention of the invalid ruling.

**11.9 Governing Law; Venue.** This Agreement and all rights and remedies hereunder shall be governed by and interpreted and enforced in accordance with the laws of the State of New York, without regard to conflict of law principles. The federal and state courts of New York shall have exclusive jurisdiction over any disputes or issues arising out of or in connection with this Agreement, and the Parties hereby irrevocably submit to such exclusive jurisdiction. Customer shall comply with all applicable laws and regulations, including but not limited to those pertaining to environmental protection and safety and health.

**11.10 Publicity; Use of Name.** Except as required by law, neither Party shall originate any publicity, news release or other public announcement, written or oral, whether to the public, press, public stockholders or otherwise, relating to this Agreement, to any amendment hereto or thereto or activities hereunder or thereunder without the prior written consent of the other Party. Nothing contained in this Agreement shall be construed as conferring any right to

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use in advertising, publicity or other promotional activities any name, trade name, trademark, or other designation (including any contraction, abbreviation, or simulation of any of the foregoing); and each Party hereto agrees not to use any designation of the other Party in any promotional activity associated with this Agreement without the express written approval of the other Party.

**11.11 Counterparts; Evidence of Signature.** This Agreement may be executed in separate counterparts, each of which shall be identical and may be introduced in evidence or used for any other purpose without any other counterpart, but all of which shall together constitute one and the same agreement. Signatures of any Party transmitted by facsimile or electronic mail (including, without limitation, electronic mailing of a so-called portable document format or “pdf” of a scanned counterpart) shall be treated as and deemed to be original signatures for all purposes, and shall have the same binding effect as if they were original, signed instruments delivered in person.

**11.12 Entire Agreement.** This Agreement, together with all Attachments referenced herein, constitutes the entire understanding and agreement of the Parties hereto with respect to the matters described herein and supersedes all prior agreements or understandings, written or oral, between the Parties with respect thereto.

**11.13 Conflicts; Order of Preference.** In the event any subject matter addressed in Sections 1 – 11 of this Agreement are also addressed in any Attachment, then all of such provisions shall remain applicable to such subject matter to the maximum extent possible, with the more specific controlling over that which is more general. In the event that there is an actual conflict between any provision of Sections 1 – 11 of this Agreement and any provision(s) of any Attachment(s), then the provisions of Sections 1 – 11 shall prevail. In the event of a conflict between this Agreement and the Quality Agreement, the conflict shall be resolved in accordance with Section 2.6 hereof.

**11.14 Amendment or Waiver.** Notwithstanding any course of performance hereunder or other course of dealing, any amendment to or waiver of any provision of this Agreement must be in writing signed by each Party, and must specifically refer to the provision of the Agreement being amended or waived in order to be effective. Any purported amendment or waiver, whether oral, by electronic communication including emails between Parties, by conduct, custom shall not constitute a writing sufficient to amend this Agreement. The Parties are expressly and deliberately establishing these procedures specifically to avoid any possibility that an amendment, waiver or estoppel of or with respect to any of this Agreement’s terms could be deemed to have been affected in a manner other than as set forth in this Section.

**11.15 Translations.** In the event of an inconsistency between any terms of this Agreement and any translations thereof into another language, the English language meaning shall control.

**11.16 Export Compliance.** The Parties shall abide by the applicable export regulations of the United States and any other country or countries. If required, the Party intending to export controlled technology or data (including a “deemed” export) shall apply for an export license or other suitable authorization from the proper authority prior to any such export and inform any Receiving Party of any further restrictions on use of the technology or data. The Parties shall not export or re-export any technical data, products, or samples received from the disclosing Party or the direct product of such technical data in contravention of the export compliance laws of the United States or associated regulations.

<Signatures follow on next page.>

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IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by their duly authorized representatives, effective as of the Effective Date.

**EVONIK CORPORATION**

By: /s/ Robert J. Koprowski  
Name: Robert J. Koprowski  
Title: Director  
Date: February 28, 2014

**AKEBIA THERAPEUTICS, INC.**

By: /s/ John P. Butler  
Name: John P. Butler  
Title: CEO  
Date: February 28, 2014

**ATTACHMENT A**

**PROPOSAL [Insert Proposal Number]  
[Insert Proposal Title]**

**THIS PROPOSAL** (as defined in the Master Services Agreement by and between Akebia Therapeutics, Inc. (“Customer”) and Evonik Corporation (“Evonik”) dated and hereinafter “Agreement”) upon execution will be incorporated into the Agreement and subject to the terms and conditions in the Agreement and shall become effective as of the date of last signature. All capitalized terms in this Proposal shall have the same meaning as set forth in the Agreement. Any changes to the Proposal will require a written and agreed Change Order as specified in Section 2.2 of the Agreement.

Customer hereby engages Evonik to provide the following services and Evonik hereby agrees to provide such services for the compensation outlined below.

1. Services: Evonik shall provide the services as described below: [services to be described].
2. Estimated Timeline: The estimated time to complete the services described in the Proposal is [insert length of time].
3. Estimated Budget and Prepayment: The Estimated Budget for this Proposal is [Insert \$] and the Prepayment is [Insert \$].

This Proposal [Insert Proposal #], upon execution by both parties shall constitute an amendment and an additional Proposal to the Agreement pursuant to Section 11.15 of the Agreement and shall hereinafter be part of the Agreement and attached as Attachment [X].

[This Proposal contains information that is proprietary to Evonik.]

**AGREED TO AND ACCEPTED BY:**

**EVONIK CORPORATION**

By: \_\_\_\_\_  
Printed Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**AKEBIA THERAPEUTICS, INC.**

By: \_\_\_\_\_  
Printed Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

**ATTACHMENT B**

**Part 1 - Commercial Proposals for Akebia Product AKB-6548**

**Proposals and Status as of March 3, 2014**

**(A copy of each of the following documents and POs is attached.)**

<u>Proposal</u>	<u>Description</u>	<u>Remarks</u>	<u>PO</u>	<u>PO Issued</u>	<u>Current Status</u>	<u>Cost</u>
<b>B-1</b>	Lab familiarization of AKB-6548	Subsets of document entitled "Proposal for Akebia AKB-6548" dated September 25, 2013 as indicated with "OK to Proceed" and on signature page.	1525	2013-10-15	Completed	[***]
	Optimization of [***]		1526	2013-10-15	Ongoing	[***]
<b>B-2</b>	Optimization of AKB-6548 Synthesis, steps [***]	Subsets of above document, as indicated on signature page.	1529	2013-11-05	Ongoing	[***]
	Analytics for raw materials, IPCs, intermediates		1530	2013-11-05	Ongoing	[***]
	Analytics for API		1531	2013-11-05	Ongoing	[***]
<b>B-3</b>	16 Kg Non-GMP demo batch (cost raw materials only)	Subsets of above document, as indicated on signature page.	1540	2013-12-03	Completed	Not to exceed [***]
	16 Kg Non-GMP demo batch (cost for plant reservation)		1539	2013-12-03	N/A	[***]
<b>B-4</b>	"Proposal for Akebia AKB-6548" dated January 3, 2014 re: 2 Gallon scale up of AKB-6548	Entire document.	1548	2014-01-08	Ongoing	[***]
<b>B-5</b>	"Proposal for Manufacturing Approximately 16 kg of Non-GMP AKB-6548"	Entire document.	n/a	n/a	n/a	Per proposal
<b>B-6</b>	"Proposal for Manufacturing AT Least 350 kg of GMP AKB-6548"	Entire document.	n/a	n/a	n/a	Per proposal

(See attached for each.)



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**PROPOSAL B-1: PROPOSAL FOR AKEBIA AKB-6548**

Thank you for considering Evonik Corporation for the development and production of AKB-6548. Evonik believes this is a good fit from both a technical and strategic perspective. The synthesis to do the Demo, Engineering and Registration batches will be run at our Tippecanoe Laboratories located in Lafayette, Indiana. To expedite the development and provide Akebia with the best value, the development will be conducted at 2 sites, Lafayette Indiana and Hanau, Germany.

The quote provided is based on the technical package transferred by Akebia as well as experience gained at Evonik running our production facility.

The process can be run as is described in the technical package. However, potential improvements could be envisioned with an abbreviated development program. If realized, a more efficient process would be achieved from the variable and fixed costs.

The prices are based on the following assumptions:

- Evonik will purchase all necessary raw materials
- Production will be done under cGMPs for API manufacture.
- The development program set forth below is suggested but Evonik and Akebia will determine the actual scope of the experimentation and have conversations throughout development.
- Methanol is assumed to be an appropriate cleaning solvent.
- Basis for the evaluation: tech package provided on August 8th, 2013 and RFP received in August 28th, 2013.
- cCMP production of 350 kg of AKB-6548 and its release as 3 batches of approximately equal size and appropriate use as Phase 3 clinical trials.
- Material and registration batches to be available by the end of September 2014.
- Development work to improve process robustness as well as DoE studies to identify and define appropriate operational ranges for each step of the synthesis.
- An optional 15-20 kg non-GMP campaign to ensure robustness and address scale up issues.
- Identify appropriate storage conditions and stability studies for isolated intermediates and API post GMP production.
- Payment terms are 30 days.
- Analytical methods for the raw materials, intermediates and IPCs will be transferred to Evonik.
- Synthesis of reference standards and impurities as well as solvent recovery is not included

**Development Opportunities**

The following areas of the process including technical transfer, improvements to the individual step, evaluation of the Suzuki coupling and refinement of the final crystallization have been

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identified in order to enhance robustness of the current manufacturing route. Areas targeted for experimentation are defined below.

**Technical Transfer of the manufacturing route**

Familiarization with the existing process

Evonik will run a process familiarization on the existing process at a cost of [\*\*\*] dollars.

Development Work

In addition, Evonik suggests optimizing steps [\*\*\*] by modifying the current procedure for material isolation to improve throughput and equipment usage. This work will be performed in Tippecanoe at a price of [\*\*\*].

[\*\*\*]

Perform experiment in two gallon to provide material for subsequent steps.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries. This will be followed by 1 to 2 scale-up experiments.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries. This development will also include screening of different reaction conditions.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries.

[\*\*\*]

Run 1-2 experiments to provide enough material for at least 5 experiments. Followed by work-up optimization studies to target lower volumes and avoid reslurry.

**Technical Improvements**

In addition to the development work cited above, the following chemistry experimentation is recommended to further enhance the process.

[\*\*\*]

[\*\*\*] screening will be performed at Hanau. Evonik suggests the screening of different ligands, base, solvents and [\*\*\*] for the reaction. The initial screening experiments will cost [\*\*\*]

In addition Evonik would perform a study on the [\*\*\*] loading and solvent amount as previous studies reported lower reaction rates at higher concentrations. This is a well know phenomena related to [\*\*\*] formation and may indicate excess [\*\*\*]. These studies would cost [\*\*\*].

Furthermore the work up would be improved to avoid slurries at a cost of [\*\*\*].

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[\*\*\*]

Evonik will suggest screening of several [\*\*\*] in order to optimize the reaction kinetics and the impurity profile. Most of the work will be performed at Tippcanoe laboratories.

[\*\*\*]

Evonik suggests the development of a [\*\*\*] procedure as the current method [\*\*\*] on several occasions. The price will include delivery of phase diagrams, solubility study on the material, characterization of polymorph forms and crystallization process investigation with FBRM-PVM. The total costs associated with the studies including analytics are \$[\*\*\*] which includes [\*\*\*].

#### Particle Size and Polymorphism

The above isolation studies of the API will also incorporate polymorphism and particle size studies.

#### Manufacturing Improvements and Engineering studies

The manufacturing studies and engineering studies envisioned based on the tech package are listed above. Evonik will also determine bulk densities, melting points and other physical data as required for production. Additional studies may be required based on the actual performance of the material in the laboratory.

Use tests of raw materials will be done directly prior to manufacturing as the key raw materials cannot be utilized from the “on-scale” supplier for the lab development work due to long lead times.

The operational design space, identification of critical parameters and associated proven acceptable ranges requires an intense discussion between Akebia and Evonik. Therefore, this price is only meant to be an indication based on Evonik’s experience with other customers and the current technical package. Evonik suggests using material from the pilot campaign for the DoE experiments as this would allow for a better assessment. The cost for DoE experimentation is estimated at [\*\*\*] per step. This includes use tests in the subsequent step and analytics in the QC department.

#### Approach to ICH guidelines for implementation of Quality by Design

Evonik will facilitate NDA submission by performing general optimization experiments and DoE studies. DoE experiments will be performed in each step as follows:

Part 1. General optimization work and DoE studies screening different parameters (e.g., temperature, concentrations, dosing times and amount of reagents).

Part 2. Proven and acceptable ranges (PARs) for the critical process parameters (CPPs) identified in Part 1 will be determined in larger scale experiments. In addition factorial design in case of interactions between the CPPs will be performed.

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Based on the current technical information, we suggest controlling the following parameters:

B503 (RSM): NMR, HPLC (assay and impurity profile), water (KF), ([\*\*\*]) (visual substance specific test) and LOD to be discussed)

B504, B505: NMR, HPLC (assay and impurity profile), additionally water (KF) for B 504

IPCs for all synthetic steps (HPLC or TLC)

AKB-6548 according to current specification: NMR, IR, HPLC (assay and impurity profile), Water (KF), residual solvents, heavy metals (ICP-MS), ROI or other testing as found appropriate during the development work.

Additional analytical methods

Evonik will perform additional analytical method development work were appropriate. Prices for this type of work strongly depend on the necessity of validation work (GMP vs. non-GMP) and the type of method (e.g. standard impurities vs. GTIs on ppm level). Evonik will discuss with Akebia the need for any additional analytical method development as it is discovered throughout the campaign.

Raw material supplier identification

Evonik identifies raw material suppliers during the RFP phase. After receiving a PO, Evonik typically requests samples from potential suppliers and selects suitable suppliers. Depending on the criticality of the raw materials Evonik may then also may perform audits following discussion with Akebia regarding the need and costs.

Proof of Concept

A proof of concept study would be performed in Evonik's Tippecanoe laboratories using 2 gallon equipment. The costs associated with this study are [\*\*\*].

Pilot Campaign

Evonik suggests performing a pilot campaign to have a better understanding of scale up effects as well as to provide material for formulation studies. In addition, material on each step (500 g to 1 kg) could be employed for DOE studies as mentioned above. The costs and timeline associated with the Pilot Campaign are described in the table below. Target after sampling on each step would be 5-8 kg. The cost for the Pilot Campaign is [\*\*\*].

B503 as regulatory API starting material

The actual amount of work required to provide the FDA with sufficient information to allow the registration of B503 as registered starting material is highly chemistry dependent. Due to the fact that there are still [\*\*\*] chemical steps and [\*\*\*] to [\*\*\*] steps up to the API our experience is that the requirements are less strict than with fewer chemical conversions. However, we will

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need to control all GTI's and non-rejectable impurities in B503. Therefore, we need to establish the appropriate analytical method. Impurities can likely be detected via HPLC and therefore do not require significant additional work. Traces of impurities (e.g. CTIs) might need more sophisticated methods to be established due to the level of control. For example, HPLC-MS or GC-MS would need to be established. The cost per method is approximately [\*\*\*].

Evonik assumes that the process development work will be able to cover the appropriate rejection strategies for the impurities including GTI's as well as the [\*\*\*] content.

Storage conditions for intermediates

Evonik will work in close collaboration with Akebia to decide on the storage conditions. The conditions will be likely established during the development work. Based on typical storage conditions, study length and analytical parameters monitored, the costs associated would be about [\*\*\*] for intermediates and API-SM. All testing will be performed in the process development laboratories. Upon discussions with Akebia, the final assessment will be determined.

Analytical method transfer for Raw materials, intermediates and IPCs

The cost associated with the transfer and validation of analytical for the raw material, intermediates and IPC methods is [\*\*\*].

Analytical method transfer for the API

The cost associated with the transfer and validation of analytical methods for the API is [\*\*\*].

FDA filing requirements for analytical methods

Evonik will do validation work but currently does not foresee the need for any additional development work on the analytical methods.

Development Reports

Evonik will draft a development report prior to manufacturing as a basis for decision making for unplanned events during manufacturing. These reports will be sent to Akebia for review. The costs for this are already included in the development work costs.

Outsourcing

Evonik does not currently see the need for outsourcing any of the work as all of the work required currently can be done in house.

Communication of R&D progress

The Evonik Project Team will have weekly or biweekly telecons with Akebia. These meetings will include short summaries of the work performed in the last week and a meeting summary with action items prepared by Evonik.

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In addition, the project manager (and if preferred by Akebia other team members) will be in contact with Akebia via email and telephone as necessary.

**Manufacturing of 350 kg of AKB-6548**

Costs for scale up

In addition to the development and laboratory familiarization studies described above some safety studies may be required. The costs associated with these studies will depend on the availability of data from previous campaigns. Typically Evonik requires DSC's and RCI's (ca. [\*\*\*] and ca. [\*\*\*]) prior to scale up therefore about [\*\*\*] per step or a total of [\*\*\*] may be required.

Manufacturing Support

Manufacturing support and value creating activities such as mass balances are typically included in the manufacturing costs for the initial campaigns.

Scale Up Details

The production of the 350 kg would take place in plants T27 and T31 at our Tippecanoe site. This assumes significant improvements to the volume for the final step.

Timeline constraints may be caused by overcommitted raw material suppliers. Evonik attempts to mitigate this risk by identifying more than one source for all raw materials. In addition, detection of GTIs or new impurities for which no information is known poses a potential timing risk. Recrystallization could potentially remove the impurities but could affect the production timing.

No Capital costs are expected for this project.

Production of 350 kg API

The costs for manufacturing the 3 registration batches of 350 kg AKB- 6548 is [\*\*\*]/kg. The material will be produced under cGMP conditions and Evonik will provide a COA as well as electronic copies of the batch records. If an additional batch of each step is performed as an engineering batch during this campaign at the same scale, the cost will be [\*\*\*]/kg.

In the previous proposal, the cost for production of the registration batches was [\*\*\*]/kg. There are 2 reasons the price has increased. Firstly, the variable costs have risen from [\*\*\*] per kg in the initial proposal to [\*\*\*] per kg currently. Secondly, to run the 350 kg registration campaign, the reactors are only at [\*\*\*] fill volume. This has doubled the fixed costs per kg. If Evonik were to produce 700 kg of material in the 3 registration batches, the price will be approximately [\*\*\*] per kg which represents the difference in the variable cost when compared to the last campaign.

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Akebia and Evonik will work together to lower the costs of the key raw materials, which lead to the high variable costs. In the event that qualified suppliers can be identified at a lower price, the cost savings will be passed through to Akebia.

Stability Study

The costs for the API stability studies are [\*\*\*]. Evonik assumes following:

- 1 long-term stability condition for 8 timepoints plus zero timepoint;
- 1 accelerated stability condition for 5 timepoints plus zero timepoint. Testing will include physical appearance, KF, LC, XRPD.

Summary of Costs

<u>Objective</u>	<u>Costs [\$]</u>	<u>Location</u>
Laboratory Familiarization	[***]	Tippe
Optimization step [***]	[***]	Tippe
[***] screening and work up (incl. [***] determination)	[***]	Hanau
Isolation of API (crystallization studies incl [***] determination)	[***]	Hanau
Sample on 2 gallon scale (PoC)	[***]	Tippe
Total Development Costs	[***]	Tippe/Hanau
DOE Studies of 3 steps (indication only)	[***]	Hanau
Analytics for Raws, IPCs, Intermediates	[***]	Tippe
Analytics for API	[***]	Tippe
Stability Studies	[***]	Tippe
Analytics (total)	[***]	Tippe
Demo Batches	[***]	Tippe
Registration Batches (3 Batches) 350 kg	[***]/kg	Tippe
1 Demo plus 3 Registration Batches (4 Batches) 470 kg	[***]/kg	Tippe

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REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

The PO is needed for this project by October 11, 2013 in order to start the project and guarantee the slot in the facility. Payment terms are net 30.

Should you have any questions regarding this quotation, please feel free to contact me.

Thank you again for your consideration and Evonik looks forward to hearing from you soon and being a part of this Akebia project.

Thank You and Best Regards,

/s/ Joseph D'Antuono, PhD

Joseph D'Antuono, PhD  
Key Account Director  
Health Care

APPROVED FOR:

(1) PROCESS FAMILIARIZATION: [\*\*\*]

(2) [\*\*\*]: [\*\*\*]

TOTAL: [\*\*\*]

SIGNED: /s/John P. Butler

TITLE:



**PROPOSAL B-2: PROPOSAL FOR AKEBIA AKB-6548**

Thank you for considering Evonik Corporation for the development and production of AKB-6548. Evonik believes this is a good fit from both a technical and strategic perspective. The synthesis to do the Demo, Engineering and Registration batches will be run at our Tippecanoe Laboratories located in Lafayette, Indiana. To expedite the development and provide Akebia with the best value, the development will be conducted at 2 sites, Lafayette Indiana and Hanau, Germany.

The quote provided is based on the technical package transferred by Akebia as well as experience gained at Evonik running our production facility.

The process can be run as is described in the technical package. However, potential improvements could be envisioned with an abbreviated development program. If realized, a more efficient process would be achieved from the variable and fixed costs.

The prices are based on the following assumptions:

- Evonik will purchase all necessary raw materials
- Production will be done under cGMPs for API manufacture.
- The development program set forth below is suggested but Evonik and Akebia will determine the actual scope of the experimentation and have conversations throughout development.
- Methanol is assumed to be an appropriate cleaning solvent.
- Basis for the evaluation: tech package provided on August 8th, 2013 and RFP received in August 28th, 2013.
- cCMP production of 350 kg of AKB-6548 and its release as 3 batches of approximately equal size and appropriate use as Phase 3 clinical trials.
- Material and registration batches to be available by the end of September 2014.
- Development work to improve process robustness as well as DoE studies to identify and define appropriate operational ranges for each step of the synthesis.
- An optional 15-20 kg non-GMP campaign to ensure robustness and address scale up issues.
- Identify appropriate storage conditions and stability studies for isolated intermediates and API post GMP production.
- Payment terms are 30 days.
- Analytical methods for the raw materials, intermediates and IPCs will be transferred to Evonik.
- Synthesis of reference standards and impurities as well as solvent recovery is not included

**Development Opportunities**

The following areas of the process including technical transfer, improvements to the individual step, evaluation of the Suzuki coupling and refinement of the final crystallization have been

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identified in order to enhance robustness of the current manufacturing route. Areas targeted for experimentation are defined below.

**Technical Transfer of the manufacturing route**

Familiarization with the existing process

OK TO PROCEED

Evonik will run a process familiarization on the existing process at a cost of [\*\*\*] dollars.

Development Work

In addition, Evonik suggests optimizing steps [\*\*\*] by modifying the current procedure for material isolation to improve throughput and equipment usage. This work will be performed in Tippecanoe at a price of [\*\*\*].

[\*\*\*]

Perform experiment in two gallon to provide material for subsequent steps.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries. This will be followed by 1 to 2 scale-up experiments.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries. This development will also include screening of different reaction conditions.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries.

[\*\*\*]

Run 1-2 experiments to provide enough material for at least 5 experiments. Followed by work-up optimization studies to target lower volumes and avoid reslurry.

**Technical Improvements**

In addition to the development work cited above, the following chemistry experimentation is recommended to further enhance the process.

[\*\*\*]

OK TO PROCEED

[\*\*\*] screening will be performed at Hanau. Evonik suggests the screening of different ligands, base, solvents and [\*\*\*] for the reaction. The initial screening experiments will cost [\*\*\*]

OK TO PROCEED

In addition Evonik would perform a study on the [\*\*\*] loading and solvent amount as previous studies reported lower reaction rates at higher concentrations. This is a well know phenomena related to [\*\*\*] formation and may indicate excess catalyst. These studies would cost [\*\*\*].

OK TO PROCEED

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Furthermore the work up would be improved to avoid slurries at a cost of [\*\*\*].

[\*\*\*]

Evonik will suggest screening of several [\*\*\*] in order to optimize the reaction kinetics and the impurity profile. Most of the work will be performed at Tippcanoe laboratories.

[\*\*\*]

Evonik suggests the development of a [\*\*\*] procedure as the current method [\*\*\*] on several occasions. The price will include delivery of phase diagrams, solubility study on the material, characterization of polymorph forms and crystallization process investigation with FBRM-PVM. The total costs associated with the studies including analytics are \$[\*\*\*] which includes [\*\*\*].

#### Particle Size and Polymorphism

The above isolation studies of the API will also incorporate polymorphism and particle size studies.

#### Manufacturing Improvements and Engineering studies

The manufacturing studies and engineering studies envisioned based on the tech package are listed above. Evonik will also determine bulk densities, melting points and other physical data as required for production. Additional studies may be required based on the actual performance of the material in the laboratory.

Use tests of raw materials will be done directly prior to manufacturing as the key raw materials cannot be utilized from the “on-scale” supplier for the lab development work due to long lead times.

The operational design space, identification of critical parameters and associated proven acceptable ranges requires an intense discussion between Akebia and Evonik. Therefore, this price is only meant to be an indication based on Evonik’s experience with other customers and the current technical package. Evonik suggests using material from the pilot campaign for the DoE experiments as this would allow for a better assessment. The cost for DoE experimentation is estimated at [\*\*\*] per step. This includes use tests in the subsequent step and analytics in the QC department.

#### Approach to ICH guidelines for implementation of Quality by Design

Evonik will facilitate NDA submission by performing general optimization experiments and DoE studies. DoE experiments will be performed in each step as follows:

Part 1. General optimization work and DoE studies screening different parameters (e.g., temperature, concentrations, dosing times and amount of reagents).

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Part 2. Proven and acceptable ranges (PARs) for the critical process parameters (CPPs) identified in Part 1 will be determined in larger scale experiments. In addition factorial design in case of interactions between the CPPs will be performed.

Based on the current technical information, we suggest controlling the following parameters:

B503 (RSM): NMR, HPLC (assay and impurity profile), water (KF), ([\*\*\*]) (visual substance specific test) and LOD to be discussed)

B504, B505: NMR, HPLC (assay and impurity profile), additionally water (KF) for B 504

IPCs for all synthetic steps (HPLC or TLC)

AKB-6548 according to current specification: NMR, IR, HPLC (assay and impurity profile), Water (KF), residual solvents, heavy metals (ICP-MS), ROI or other testing as found appropriate during the development work.

Additional analytical methods

Evonik will perform additional analytical method development work were appropriate. Prices for this type of work strongly depend on the necessity of validation work (GMP vs. non-GMP) and the type of method (e.g. standard impurities vs. GTIs on ppm level). Evonik will discuss with Akebia the need for any additional analytical method development as It is discovered throughout the campaign.

Raw material supplier identification

Evonik identifies raw material suppliers during the RFP phase. After receiving a PO, Evonik typically requests samples from potential suppliers and selects suitable suppliers. Depending on the critically of the raw materials Evonik may then also may perform audits following discussion with Akebia regarding the need and costs.

Proof of Concept

A proof of concept study would be performed in Evonik's Tippecanoe laboratories using 2 gallon equipment. The costs associated with this study are [\*\*\*].

Pilot Campaign

Evonik suggests performing a pilot campaign to have a better understanding of scale up effects as well as to provide material for formulation studies. In addition, material on each step (500 g to 1 kg) could be employed for DOE studies as mentioned above. The costs and timeline associated with the Pilot Campaign are described in the table below. Target after sampling on each step would be 5-8 kg. The cost for the Pilot Campaign is [\*\*\*].

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B503 as regulatory API starting material

The actual amount of work required to provide the FDA with sufficient information to allow the registration of B503 as registered starting material is highly chemistry dependent. Due to the fact that there are still [\*\*\*] chemical steps and [\*\*\*] to [\*\*\*] steps up to the API our experience is that the requirements are less strict than with fewer chemical conversions. However, we will need to control all GTI's and non-rejectable impurities in B503. Therefore, we need to establish the appropriate analytical method. Impurities can likely be detected via HPLC and therefore do not require significant additional work. Traces of impurities (e.g CTIs) might need more sophisticated methods to be established due to the level of control. For example, HPLC-MS or GC-MS would need to be established. The cost per method is approximately [\*\*\*].

Evonik assumes that the process development work will be able to cover the appropriate rejection strategies for the impurities including GTI's as well as the [\*\*\*] content.

Storage conditions for intermediates

Evonik will work in close collaboration with Akebia to decide on the storage conditions. The conditions will be likely established during the development work. Based on typical storage conditions, study length and analytical parameters monitored, the costs associated would be about [\*\*\*] for intermediates and API-SM. All testing will be performed in the process development laboratories. Upon discussions with Akebia, the final assessment will be determined.

Analytical method transfer for Raw materials, intermediates and IPCs

The cost associated with the transfer and validation of analytical for the raw material, intermediates and IPC methods is [\*\*\*].

Analytical method transfer for the API

The cost associated with the transfer and validation of analytical methods for the API is [\*\*\*].

FDA filing requirements for analytical methods

Evonik will do validation work but currently does not foresee the need for any additional development work on the analytical methods.

Development Reports

Evonik will draft a development report prior to manufacturing as a basis for decision making for unplanned events during manufacturing. These reports will be sent to Akebia for review. The costs for this are already included in the development work costs.

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Outsourcing

Evonik does not currently see the need for outsourcing any of the work as all of the work required currently can be done in house.

Communication of R&D progress

The Evonik Project Team will have weekly or biweekly telecons with Akebia. These meetings will include short summaries of the work performed in the last week and a meeting summary with action items prepared by Evonik.

In addition, the project manager (and if preferred by Akebia other team members) will be in contact with Akebia via email and telephone as necessary.

**Manufacturing of 350 kg of AKB-6548**

Costs for scale up

In addition to the development and laboratory familiarization studies described above some safety studies may be required. The costs associated with these studies will depend on the availability of data from previous campaigns. Typically Evonik requires DSC's and RCI's (ca. [\*\*\*] and ca. [\*\*\*]) prior to scale up therefore about [\*\*\*] per step or a total of [\*\*\*] may be required.

Manufacturing Support

Manufacturing support and value creating activities such as mass balances are typically included in the manufacturing costs for the initial campaigns.

Scale Up Details

The production of the 350 kg would take place in plants T27 and T31 at our Tippecanoe site. This assumes significant improvements to the volume for the final step.

Timeline constraints may be caused by overcommitted raw material suppliers. Evonik attempts to mitigate this risk by identifying more than one source for all raw materials. In addition, detection of GTIs or new impurities for which no information is known poses a potential timing risk. Recrystallization could potentially remove the impurities but could affect the production timing.

No Capital costs are expected for this project.

Production of 350 kg API

The costs for manufacturing the 3 registration batches of 350 kg AKB- 6548 is [\*\*\*/kg. The material will be produced under cGMP conditions and Evonik will provide a COA as well as electronic copies of the batch records. If an additional batch of each step is performed as an engineering batch during this campaign at the same scale, the cost will be [\*\*\*/kg.

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REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
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In the previous proposal, the cost for production of the registration batches was [\*\*\*/kg. There are 2 reasons the price has increased. Firstly, the variable costs have risen from [\*\*\*] per kg in the initial proposal to [\*\*\*] per kg currently. Secondly, to run the 350 kg registration campaign, the reactors are only at [\*\*\*] fill volume. This has doubled the fixed costs per kg. If Evonik were to produce 700 kg of material in the 3 registration batches, the price will be approximately [\*\*\*] per kg which represents the difference in the variable cost when compared to the last campaign.

Akebia and Evonik will work together to lower the costs of the key raw materials, which lead to the high variable costs. In the event that qualified suppliers can be identified at a lower price, the cost savings will be passed through to Akebia.

Stability Study

The costs for the API stability studies are [\*\*\*]. Evonik assumes following:

- 1 long-term stability condition for 8 timepoints plus zero timepoint;
- 1 accelerated stability condition for 5 timepoints plus zero timepoint. Testing will include physical appearance, KF, LC, XRPD.

Summary of Costs

<u>Objective</u>	<u>Costs [\$]</u>	<u>Location</u>
Laboratory Familiarization	[***]	Tippe
Optimization step [***]	[***]	Tippe
[***] screening and work up (incl. [***] determination)	[***]	Hanau
Isolation of API (crystallization studies incl [***] determination)	[***]	Hanau
Sample on 2 gallon scale (PoC)	[***]	Tippe
Total Development Costs	[***]	Tippe/Hanau
DOE Studies of 3 steps (indication only)	[***]	Hanau
Analytics for Raws, IPCs, Intermediates	[***]	Tippe
Analytics for API	[***]	Tippe
Stability Studies	[***]	Tippe
Analytics (total)	[***]	Tippe
Demo Batches	[***]	Tippe
Registration Batches (3 Batches) 350 kg	[***/kg	Tippe
1 Demo plus 3 Registration Batches (4 Batches) 470 kg	[***/kg	Tippe

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REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

The PO is needed for this project by October 11, 2013 in order to start the project and guarantee the slot in the facility. Payment terms are net 30.

Should you have any questions regarding this quotation, please feel free to contact me.

Thank you again for your consideration and Evonik looks forward to hearing from you soon and being a part of this Akebia project.

Thank You and Best Regards,

/s/ Joseph D'Antuono, PhD

Joseph D'Antuono, PhD  
Key Account Director  
Health Care

APPROVED FOR THE FOLLOWING TASKS ONLY:

(1) OPTIMIZATION OF [\*\*\*]:[\*\*\*]

(2) ANALYTICS FOR RMs, IPCs, ETC: [\*\*\*]

(3) ANALYTICS FOR API: [\*\*\*]

TOTAL: [\*\*\*]

SIGNED: /s/Mitch Antoon

TITLE: MANAGER, CMC DATE: 5-NOV-2013



**PROPOSAL B-3: PROPOSAL FOR AKEBIA AKB-6548**

Thank you for considering Evonik Corporation for the development and production of AKB-6548. Evonik believes this is a good fit from both a technical and strategic perspective. The synthesis to do the Demo, Engineering and Registration batches will be run at our Tippecanoe Laboratories located in Lafayette, Indiana. To expedite the development and provide Akebia with the best value, the development will be conducted at 2 sites, Lafayette Indiana and Hanau, Germany.

The quote provided is based on the technical package transferred by Akebia as well as experience gained at Evonik running our production facility.

The process can be run as is described in the technical package. However, potential improvements could be envisioned with an abbreviated development program. If realized, a more efficient process would be achieved from the variable and fixed costs.

The prices are based on the following assumptions:

- Evonik will purchase all necessary raw materials
- Production will be done under cGMPs for API manufacture.
- The development program set forth below is suggested but Evonik and Akebia will determine the actual scope of the experimentation and have conversations throughout development.
- Methanol is assumed to be an appropriate cleaning solvent.
- Basis for the evaluation: tech package provided on August 8th, 2013 and RFP received in August 28th, 2013.
- cCMP production of 350 kg of AKB-6548 and its release as 3 batches of approximately equal size and appropriate use as Phase 3 clinical trials.
- Material and registration batches to be available by the end of September 2014.
- Development work to improve process robustness as well as DoE studies to identify and define appropriate operational ranges for each step of the synthesis.
- An optional 15-20 kg non-GMP campaign to ensure robustness and address scale up issues.
- Identify appropriate storage conditions and stability studies for isolated intermediates and API post GMP production.
- Payment terms are 30 days.
- Analytical methods for the raw materials, intermediates and IPCs will be transferred to Evonik.
- Synthesis of reference standards and impurities as well as solvent recovery is not included

**Development Opportunities**

The following areas of the process including technical transfer, improvements to the individual step, evaluation of the Suzuki coupling and refinement of the final crystallization have been

identified in order to enhance robustness of the current manufacturing route. Areas targeted for experimentation are defined below.

#### **Technical Transfer of the manufacturing route**

##### Familiarization with the existing process

Evonik will run a process familiarization on the existing process at a cost of [\*\*\*] dollars.

##### Development Work

In addition, Evonik suggests optimizing steps [\*\*\*] by modifying the current procedure for material isolation to improve throughput and equipment usage. This work will be performed in Tippecanoe at a price of [\*\*\*].

[\*\*\*]

Perform experiment in two gallon to provide material for subsequent steps.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries. This will be followed by 1 to 2 scale-up experiments.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries. This development will also include screening of different reaction conditions.

[\*\*\*]

Evaluate different approaches with a target of lowering the volumes and removal of the slurries.

[\*\*\*]

Run 1-2 experiments to provide enough material for at least 5 experiments. Followed by work-up optimization studies to target lower volumes and avoid reslurry.

#### **Technical Improvements**

In addition to the development work cited above, the following chemistry experimentation is recommended to further enhance the process.

[\*\*\*]

[\*\*\*]screening will be performed at Hanau. Evonik suggests the screening of different ligands, base, solvents and [\*\*\*] for the reaction. The initial screening experiments will cost [\*\*\*]

In addition Evonik would perform a study on the [\*\*\*] loading and solvent amount as previous studies reported lower reaction rates at higher concentrations. This is a well know phenomena related to [\*\*\*] formation and may indicate excess catalyst. These studies would cost [\*\*\*].

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Furthermore the work up would be improved to avoid slurries at a cost of [\*\*\*].

[\*\*\*]

Evonik will suggest screening of several [\*\*\*] in order to optimize the reaction kinetics and the impurity profile. Most of the work will be performed at Tippcanoe laboratories.

[\*\*\*]

Evonik suggests the development of a [\*\*\*] procedure as the current method [\*\*\*] on several occasions. The price will include delivery of phase diagrams, solubility study on the material, characterization of polymorph forms and crystallization process investigation with FBRM-PVM. The total costs associated with the studies including analytics are \$[\*\*\*] which includes [\*\*\*].

#### Particle Size and Polymorphism

The above isolation studies of the API will also incorporate polymorphism and particle size studies.

#### Manufacturing Improvements and Engineering studies

The manufacturing studies and engineering studies envisioned based on the tech package are listed above. Evonik will also determine bulk densities, melting points and other physical data as required for production. Additional studies may be required based on the actual performance of the material in the laboratory.

Use tests of raw materials will be done directly prior to manufacturing as the key raw materials cannot be utilized from the “on-scale” supplier for the lab development work due to long lead times.

The operational design space, identification of critical parameters and associated proven acceptable ranges requires an intense discussion between Akebia and Evonik. Therefore, this price is only meant to be an indication based on Evonik’s experience with other customers and the current technical package. Evonik suggests using material from the pilot campaign for the DoE experiments as this would allow for a better assessment. The cost for DoE experimentation is estimated at [\*\*\*] per step. This includes use tests in the subsequent step and analytics in the QC department.

#### Approach to ICH guidelines for implementation of Quality by Design

Evonik will facilitate NDA submission by performing general optimization experiments and DoE studies. DoE experiments will be performed in each step as follows:

Part 1. General optimization work and DoE studies screening different parameters (e.g., temperature, concentrations, dosing times and amount of reagents).

Part 2. Proven and acceptable ranges (PARs) for the critical process parameters (CPPs) identified in Part 1 will be determined in larger scale experiments. In addition factorial design in case of interactions between the CPPs will be performed.

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Based on the current technical information, we suggest controlling the following parameters:

B503 (RSM): NMR, HPLC (assay and impurity profile), water (KF), ([\*\*\*]) (visual substance specific test) and LOD to be discussed)

B504, B505: NMR, HPLC (assay and impurity profile), additionally water (KF) for B 504

IPCs for all synthetic steps (HPLC or TLC)

AKB-6548 according to current specification: NMR, IR, HPLC (assay and impurity profile), Water (KF), residual solvents, heavy metals (ICP-MS), ROI or other testing as found appropriate during the development work.

Additional analytical methods

Evonik will perform additional analytical method development work were appropriate. Prices for this type of work strongly depend on the necessity of validation work (GMP vs. non-GMP) and the type of method (e.g. standard impurities vs. GTIs on ppm level). Evonik will discuss with Akebia the need for any additional analytical method development as It is discovered throughout the campaign.

Raw material supplier identification

Evonik identifies raw material suppliers during the RFP phase. After receiving a PO, Evonik typically requests samples from potential suppliers and selects suitable suppliers. Depending on the critically of the raw materials Evonik may then also may perform audits following discussion with Akebia regarding the need and costs.

Proof of Concept

A proof of concept study would be performed in Evonik's Tippecanoe laboratories using 2 gallon equipment. The costs associated with this study are [\*\*\*].

Pilot Campaign

Evonik suggests performing a pilot campaign to have a better understanding of scale up effects as well as to provide material for formulation studies. In addition, material on each step (500 g to 1 kg) could be employed for DOE studies as mentioned above. The costs and timeline associated with the Pilot Campaign are described in the table below. Target after sampling on each step would be 5-8 kg. The cost for the Pilot Campaign is [\*\*\*].

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B503 as regulatory API starting material

The actual amount of work required to provide the FDA with sufficient information to allow the registration of B503 as registered starting material is highly chemistry dependent. Due to the fact that there are still [\*\*\*] chemical steps and [\*\*\*] to [\*\*\*] steps up to the API our experience is that the requirements are less strict than with fewer chemical conversions. However, we will need to control all GTI's and non-rejectable impurities in B503. Therefore, we need to establish the appropriate analytical method. Impurities can likely be detected via HPLC and therefore do not require significant additional work. Traces of impurities (e.g CTIs) might need more sophisticated methods to be established due to the level of control. For example, HPLC-MS or GC-MS would need to be established. The cost per method is approximately [\*\*\*].

Evonik assumes that the process development work will be able to cover the appropriate rejection strategies for the impurities including GTI's as well as the [\*\*\*] content.

Storage conditions for intermediates

Evonik will work in close collaboration with Akebia to decide on the storage conditions. The conditions will be likely established during the development work. Based on typical storage conditions, study length and analytical parameters monitored, the costs associated would be about [\*\*\*] for intermediates and API-SM. All testing will be performed in the process development laboratories. Upon discussions with Akebia, the final assessment will be determined.

Analytical method transfer for Raw materials, intermediates and IPCs

The cost associated with the transfer and validation of analytical for the raw material, intermediates and IPC methods is [\*\*\*].

Analytical method transfer for the API

The cost associated with the transfer and validation of analytical methods for the API is [\*\*\*].

FDA filing requirements for analytical methods

Evonik will do validation work but currently does not foresee the need for any additional development work on the analytical methods.

Development Reports

Evonik will draft a development report prior to manufacturing as a basis for decision making for unplanned events during manufacturing. These reports will be sent to Akebia for review. The costs for this are already included in the development work costs.

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Outsourcing

Evonik does not currently see the need for outsourcing any of the work as all of the work required currently can be done in house.

Communication of R&D progress

The Evonik Project Team will have weekly or biweekly telecons with Akebia. These meetings will include short summaries of the work performed in the last week and a meeting summary with action items prepared by Evonik.

In addition, the project manager (and if preferred by Akebia other team members) will be in contact with Akebia via email and telephone as necessary.

**Manufacturing of 350 kg of AKB-6548**

Costs for scale up

In addition to the development and laboratory familiarization studies described above some safety studies may be required. The costs associated with these studies will depend on the availability of data from previous campaigns. Typically Evonik requires DSC's and RCI's (ca. [\*\*\*] and ca. [\*\*\*]) prior to scale up therefore about [\*\*\*] per step or a total of [\*\*\*] may be required.

Manufacturing Support

Manufacturing support and value creating activities such as mass balances are typically included in the manufacturing costs for the initial campaigns.

Scale Up Details

The production of the 350 kg would take place in plants T27 and T31 at our Tippecanoe site. This assumes significant improvements to the volume for the final step.

Timeline constraints may be caused by overcommitted raw material suppliers. Evonik attempts to mitigate this risk by identifying more than one source for all raw materials. In addition, detection of GTIs or new impurities for which no information is known poses a potential timing risk. Recrystallization could potentially remove the impurities but could affect the production timing.

No Capital costs are expected for this project.

Production of 350 kg API

The costs for manufacturing the 3 registration batches of 350 kg AKB- 6548 is [\*\*\*]/kg. The material will be produced under cGMP conditions and Evonik will provide a COA as well as electronic copies of the batch records. If an additional batch of each step is performed as an engineering batch during this campaign at the same scale, the cost will be [\*\*\*]/kg.

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In the previous proposal, the cost for production of the registration batches was [\*\*\*]/kg. There are 2 reasons the price has increased. Firstly, the variable costs have risen from [\*\*\*] per kg in the initial proposal to [\*\*\*] per kg currently. Secondly, to run the 350 kg registration campaign, the reactors are only at [\*\*\*] fill volume. This has doubled the fixed costs per kg. If Evonik were to produce 700 kg of material in the 3 registration batches, the price will be approximately [\*\*\*] per kg which represents the difference in the variable cost when compared to the last campaign.

Akebia and Evonik will work together to lower the costs of the key raw materials, which lead to the high variable costs. In the event that qualified suppliers can be identified at a lower price, the cost savings will be passed through to Akebia.

Stability Study

The costs for the API stability studies are [\*\*\*]. Evonik assumes following:

- 1 long-term stability condition for 8 timepoints plus zero timepoint;
- 1 accelerated stability condition for 5 timepoints plus zero timepoint. Testing will include physical appearance, KF, LC, XRPD.

Summary of Costs

<u>Objective</u>	<u>Costs [\$]</u>	<u>Location</u>
Laboratory Familiarization	[***]	Tippe
Optimization step [***]	[***]	Tippe
[***] screening and work up (incl. [***] determination)	[***]	Hanau
Isolation of API (crystallization studies incl [***] determination)	[***]	Hanau
Sample on 2 gallon scale (PoC)	[***]	Tippe
Total Development Costs	[***]	Tippe/Hanau
DOE Studies of 3 steps (indication only)	[***]	Hanau
Analytics for Raws, IPCs, Intermediates	[***]	Tippe
Analytics for API	[***]	Tippe
Stability Studies	[***]	Tippe
Analytics (total)	[***]	Tippe
Demo Batches	[***]	Tippe
Registration Batches (3 Batches) 350 kg	[***]/kg	Tippe
1 Demo plus 3 Registration Batches (4 Batches) 470 kg	[***]/kg	Tippe

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REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
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The PO is needed for this project by October 11, 2013 in order to start the project and guarantee the slot in the facility. Payment terms are net 30.

Should you have any questions regarding this quotation, please feel free to contact me.

Thank you again for your consideration and Evonik looks forward to hearing from you soon and being a part of this Akebia project.

Thank You and Best Regards,

/s/ Joseph D'Antuono, PhD

Joseph D'Antuono, PhD  
Key Account Director  
Health Care

APPROVED ONLY FOR THE TASK INDICATED ON

PAGE 10, WHICH WILL BE IN 2 PARTS:

(1) RESERVE PLANT FOR MANUFACTURE OF 16KG NON-GMP AKB-  
6548: [\*\*\*]

(2) RAW MATERIALS FOR 16 KG: APPROX. [\*\*\*]

TOTAL COST: [\*\*\*]

SIGNED: /s/ John P. Butler

TITLE: CEO DATE: 11/24/13



**Proposal B-4: Proposal for Akebia AKB-6548**

Thank you for considering Evonik Corporation for the development and production of AKB-6548. Evonik believes this is a good fit from both a technical and strategic perspective. The synthesis to do the Demo, Engineering and Registration batches will be run at our Tippecanoe Laboratories located in Lafayette, Indiana. The quote provided is based on the itechnical package transferred by Akebia as well as experience gained at Evonik running our production facility.

The process can be run as is described in the technical package. However, potential improvements are being attempted during the abbreviated development program. If realized, a more efficient process would be achieved from the variable and fixed costs.

The prices are based on the following assumptions:

- Evonik will purchase all necessary raw materials.
- Production will be done under Non-cGMPs for API manufacture.
- Methanol is assumed to be an appropriate cleaning solvent.
- Basis for the evaluation: tech package provided on August 8th, 2013 and RFP received in August 28th, 2013.
- A proof of concept 2-gallon run will be done non-GMP in the Tippecanoe Laboratories. ~ 200 grams
- Identify appropriate storage conditions and stability studies for isolated intermediates and API post GMP production.
- Payment terms are 30 days.
- Analytical methods for the raw materials, intermediates and IPCs will be transferred to Evonik.
- Synthesis of reference standards and impurities as well as solvent recovery in not included

**Proof of Concept**

A proof of concept study would be performed in Evonik's Tippecanoe laboratories using 2 gallon equipment. The costs associated with this study are [\*\*\*].

The PO is needed for this project by January 15, 2014 in order to start the project and guarantee the slot in the facility. Payment terms are net 30.

Should you have any questions regarding this quotation, please feel free to contact me.

Thank you again for your consideration and Evonik looks forward to hearing from you soon and being a part of this Akebia project.

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT  
REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Thank You and Best Regards,

/s/ Joseph D'Antuono, PhD  
\_\_\_\_\_  
Joseph D'Antuono, PhD  
Key Account Director Health Care

Total Cost: [\*\*\*]  
\_\_\_\_\_

Signed: /s/ John P. Butler  
\_\_\_\_\_

Date: 1/7/2014  
\_\_\_\_\_

Title: President & CEO  
\_\_\_\_\_  
Akebia Therapeutics

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Proposal B-5: Proposal for Manufacturing Approximately 16 kg of Non-GMP AKB-6548

This *Proposal for Manufacturing Approximately 16 kg of AKB-6548* is, effective as of the date of the latest signature below, made part of that Master Services Agreement by and between Evonik Corporation (“Evonik”) and Akebia Therapeutics, Inc. (“Customer”) dated as of March 3, 2014 (“MSA”) and is a Proposal under the MSA, subject to all of the terms and conditions therein. Capitalized terms used, but not otherwise defined, in this Proposal shall have the meaning set forth in the MSA.

**1. SCOPE OF WORK**

- 1.1 Development of a detailed project plan.
- 1.2 Preparation of Master Batch Records (“MBRs”) for each step, to be reviewed and approved by Akebia.
- 1.3 Purchase of all starting materials and reagents by Evonik and vendor qualification through use testing of initially supplied representative samples of all starting materials.
- 1.4 Starting with [\*\*\*] of the starting material B517, production of approximately [\*\*\*] of AKB-6548 API in 2 lots of approximately equal size.
- 1.5 All Reference Samples will be provided by Akebia at no cost to Evonik.
- 1.6 Samples (of approximately 500 g or such other amount as mutually agreed) will be removed from certain or all of the intermediates, as determined by Akebia upon consultation with Evonik. These samples will be stored by Evonik under appropriate conditions and will be dedicated for forthcoming DOE studies (or other mutually agreed studies).
- 1.7 This material will not be produced under cGMP conditions.
- 1.8 Manufacturing of AKB-6548 is intended to verify the scalability and appropriateness of the manufacturing route.
- 1.9 Testing, release of starting materials, raw materials, isolated intermediates, and in-process control measurements as mutually agreed upon based on current optimization studies conducted at Evonik.
- 1.10 Testing and release of the AKB-6548 lots against the specification that is shown in Appendix 1 to this Proposal or as otherwise mutually agreed upon based on current optimization studies conducted at Evonik.
- 1.11 Preparation and provision of the Certificate of Analysis associated with each of the 2 lots of AKB-6548:

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REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

- 1.12 Shipment of the 2 lots of AKB-6548 on or before September 1<sup>st</sup>, 2014 to an address to be specified by Akebia.
  - 1.13 Coordination of waste disposal using either on site facilities or licensed vendors in compliance with applicable federal, state, and local regulations.
  - 1.14 Provision of project progress updates as mutually agreed upon or as needed to keep Akebia informed as to production progress. Conference calls or meetings between Evonik and Akebia will be scheduled weekly or more frequently as needed
  - 1.15 Provision of the following project documentation (collectively, "Documentation"):
    - (A) MBRs;
    - (B) Listing of process deviations and investigation results if and to the extent generated;
    - (C) Executed batch records (including analytical summary and raw data);
    - (D) Unless previously provided, copies of test procedures for releasing starting and raw materials, isolated intermediates and API and those for in-process control and cleaning measurements. Also copies of the associated specifications for this testing; and
    - (E) Batch production report with processing details sufficient to support creation of the CMC section of regulatory documents.
- 2. PRICE:**
- 2.1 The price for manufacturing and all other activities to be conducted under this Proposal, inclusive of the costs of all necessary materials and reagents, is [\*\*\*] and is fixed.
- 3. INVOICES AND PAYMENT:**
- 3.1 For the production of the targeted 16 kg less any amounts withheld for sample and future development work, Evonik will invoice Akebia as follows:
    - a) [\*\*\*] for the purchase of Key Raw Materials (PO number 1540)
    - b) [\*\*\*] to hold plant capacity for the campaign (PO Number 1539)
    - c) [\*\*\*] after successful completion of Step 3
    - d) [\*\*\*] upon completion of the campaign
    - e) [\*\*\*] upon receipt of the campaign documentation

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REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
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- 3.2 All invoices issued under this Proposal must reference the appropriate Akebia Purchase Order number provided by Akebia.
- 3.3 All amounts properly invoiced are due within thirty (30) days following receipt of invoice by Akebia.

**EVONIK CORPORATION**

By: /s/ Robert J. Koprowski  
Name: Robert J. Koprowski  
Title: Director  
Date: February 28, 2014

**AKEBIA THERAPEUTICS, INC.**

By: /s/ John P. Butler  
Name: John P. Butler  
Title: CEO  
Date: February 28, 2014

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REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED  
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**Appendix 1 (Current AKB-6548 Specification)**

<u>Test Description</u>	<u>Test ID(s)</u>	<u>Limits</u>	
Description	DESC	[***] solid	
Identification - IR (KBr)	IR	Maxima conform to those of the Standard	
Identification - HPLC	HPLCID	Retention time of the major peak in sample matches that of the major peak in the standard	
Chromatographic Impurities- HPLC	B506H2	Total Impurities: NMT [***] B640: NMT [***] B639: NMT [***] B641: NMT [***] B504: NMT [***] Any Other Individual Impurity: NMT [***]	
Assay - HPLC	B506H1	[***] %w/w s.f.a.b.	
Water Content - Karl Fischer Coulometric	KFCK	Report Only, %w/w	
Residual Solvents - GC ([***])	HSRES	[***] [***] [***] [***]	NMT [***] NMT [***] NMT [***] NMT [***]
Residual B541 assay - GC/MS	B541G1		[***]
Elemental Impurities, USP <232>: Cd, Pb, As, Hg, Ir, Pd, Pt, Rh, Ru, Cr, Mo, Ni, V and Cu	ICP	Cd Pb As Hg Ir Pd Pt Rh Ru Cr Mo Ni V Cu	[***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***]
Residual Iron	ICP	[***]	
Residue on Ignition	ROI	NMT [***]	
Melting Point	DSC	Peak onset: Report only, °C Peak Apex: Report only, °C	
X-Ray Powder Diffraction	PXRD	Diffraction pattern compares to that of the standard	

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Proposal B-6: Proposal for Manufacturing 350kg of AKB-6548

This *Proposal for Manufacturing 350kg of AKB-6548* is, effective as of the date of the latest signature below, made part of that Master Services Agreement by and between Evonik Corporation (“Evonik”) and Akebia Therapeutics, Inc. (“Customer”) dated as of March 3, 2014 (“MSA”) and is a Proposal under the MSA, subject to all of the terms and conditions therein. Capitalized terms used, but not otherwise defined, in this Proposal shall have the meaning set forth in the MSA.

**1. SCOPE OF WORK**

- 1.1 Development of a detailed project plan.
- 1.2 Preparation of Master Batch Records (“MBRs”) for each step, to be reviewed and approved by Akebia.
- 1.3 Purchase of all starting materials and reagents by Evonik and vendor qualification through use testing of initially supplied representative samples of all starting materials.
- 1.4 Commencing with the starting materials B517 ([\*\*\*] which is equivalent to [\*\*\*] of pure [\*\*\*]) and B518 ([\*\*\*] which is equivalent to [\*\*\*] of [\*\*\*]), Evonik is targeting production of 350 kg of AKB-6548. The first 3 independent lots will be of approximately equal size with a fourth lot produced from the remaining Step 3 intermediate produced. Evonik will convert the 2 starting material listed above to AKB- 6548.
- 1.5 Production is to take place under cGMP conditions.
- 1.6 Manufacturing of AKB-6548 of acceptable quality for use in phase III clinical trial and as registration batches for a NDA submission.
- 1.7 Testing and release of starting materials, raw materials, isolated intermediates and in-process control measurements with acceptance limits as mutually agreed upon based on current optimization studies conducted at Evonik.
- 1.8 Testing and release of the AKB-6548 lots against the specification that is shown in Appendix 1 to this Proposal or as otherwise mutually agreed upon based on current optimization studies conducted at Evonik.
- 1.9 Preparation and provision of the following documents associated with each of the lots of AKB-6548:
  - (A) Certificate of Analysis;

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- (B) Certification that the lot of AKB-6548 is free of BSE/TSE contamination; and
  - (C) Certificate of cGMP compliance.
- 1.10 Shipment of the lots of AKB-6548 is targeted for October 1<sup>st</sup>, 2014, to an address to be specified by Akebia. Akebia and Evonik will continue to have regular teleconferences throughout the production of AKB-6548 as indicated in 1.12 below and will determine an appropriate release and shipping strategy as production is proceeding.
- 1.11 Coordination of waste disposal using either on site facilities or licensed vendors in compliance with applicable federal, state, and local regulations. If off-site waste disposal is necessary, Evonik will pass through the costs directly to Akebia. This cost will be shared equally between Evonik and Akebia.
- 1.12 Provision of project progress updates as mutually agreed upon or as needed to keep Akebia informed as to production progress. Conference calls or meetings between Evonik and Akebia will be scheduled weekly or more frequently as needed.
- 1.13 Provision of the following project documentation (collectively, "Documentation"):
- (A) MBRs;
  - (B) Listing of process deviations and investigation results;
  - (C) Executed batch records (including analytical summary and raw data);
  - (D) Unless previously provided, copies of test procedures for releasing starting and raw materials, isolated intermediates and API and those for in-process control and cleaning measurements. Also copies of the associated specifications for this testing;
  - (E) Method validation plans and reports suitable for support of the CMC NDA filing; and
  - (F) Batch production report.
- 1.14 Support to Akebia in compiling USA and ex-USA regulatory submissions necessary to update existing submissions, including any documents requested by Akebia which were generated during the production of the campaign.
- 1.15 All Reference Samples will be provided by Akebia at no cost to Evonik.



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REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

**2. PRICE:**

- 2.1 The price for manufacturing and all other activities to be conducted under this Proposal, except the costs of materials and reagents specified in Section 2.3 or any off-site waste disposal costs, is fixed and is based for any quantity of AKB-6548 actually delivered over [\*\*\*] kg. The price is [\*\*\*]
- 2.2 If Evonik is unable to deliver [\*\*\*] kg of material from the 4 lots planned, the price of manufacturing of the material will be a prorated price (defined in Section 2.1) based on the actual quantity deliver.
- 2.3 The cost of starting materials and reagents for this campaign will be charged to Akebia at Evonik's actual cost. The current estimate of this cost is approximately [\*\*\*]/kg AKB-6548 (i.e., [\*\*\*] for the manufacture of 350kg of AKB-6548), and will not exceed [\*\*\*]- unless agreed to in writing by Akebia.
- 2.4 The preparation plan contains a contingency of 36% based on Akebia's three previous manufacturing campaigns at Alphora (not considering a recrystallization) or 19% (considering a recrystallization) in starting materials over that expected to be required for the minimum delivery quantity of 350kg of AKB-6548. Any additional AKB-6548 that is produced as a result of such contingency or improvements to the manufacturing process will be supplied to Akebia at no additional charge; that is, Akebia may not be charged for more than 350kg of AKB-6548 pursuant to this Proposal.

**3. INVOICES AND PAYMENT:**

- 3.1 For the production of 350 kg, Evonik will invoice Akebia as follows:
- A. [\*\*\*] for the purchase of Key Raw Materials upon signing this work order
  - B. [\*\*\*] to hold plant capacity for the campaign upon signing this work order
  - C. [\*\*\*] After successful completion and release of intermediate B504 (Step 3 intermediate)
  - D. [\*\*\*] upon completion of the campaign
  - E. The variable cost as defined in 2.3, less any amount invoiced under 3.1. A. upon completion of the campaign
  - F. [\*\*\*] upon receipt of the campaign documentation

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REQUEST. REDACTED MATERIAL IS MARKED WITH [\* \* \*] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

- 3.2 All invoices issued under this Proposal must reference the appropriate Akebia Purchase Order number provided by Akebia.
- 3.3 All amounts properly invoiced are due within thirty (30) days following receipt by Akebia.

**EVONIK CORPORATION**

By: /s/ Robert J. Koprowski

Name: Robert J. Koprowski

Title: Director

Date: February 28, 2014

**AKEBIA THERAPEUTICS, INC.**

By: /s/ John P. Butler

Name: John P. Butler

Title: CEO

Date: February 28, 2014

**THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT  
REQUEST. REDACTED MATERIAL IS MARKED WITH [ \* \* \* ] AND HAS BEEN FILED  
SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.**

**Appendix 1 (Current AKB-6548 Specification)**

<u>Test Description</u>	<u>Test ID(s)</u>	<u>Limits</u>	
Description	DESC	[***] solid	
Identification - IR (KBr)	IR	Maxima conform to those of the Standard	
Identification – HPLC	HPLCID	Retention time of the major peak in sample matches that of the major peak in the standard	
Chromatographic Impurities- HPLC	B506H2	Total Impurities: NMT [***] [***] [***] [***] Any Other Individual Impurity: [***] %w/w	
Assay - HPLC	B506H1	[***] %w/w s.f.a.b.	
Water Content - Karl Fischer Coulometric	KFCK	Report Only, %w/w	
Residual Solvents - GC ([***])	HSRES	[***] [***] [***] [***]	NMT [***] NMT [***] NMT [***] NMT [***]
Residual B541 assay - GC/MS	B541G1		[***]
Elemental Impurities, USP <232>: Cd, Pb, As, Hg, Ir, Pd, Pt, Rh, Ru, Cr, Mo, Ni, V and Cu	ICP	Cd Pb As Hg Ir Pd Pt Rh Ru Cr Mo Ni V Cu	[***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***] [***]
Residual Iron	ICP	[***]	
Residue on Ignition	ROI	NMT [***]	
Melting Point	DSC	Peak onset: Report only, °C Peak Apex: Report only, °C	
X-Ray Powder Diffraction	PXRD	Diffraction pattern compares to that of the standard	

**Consent of Independent Registered Public Accounting Firm**

We consent to the reference to our firm under the caption “Experts” and to the use of our report dated February 14, 2014, in Amendment No. 1 to the Registration Statement (Form S-1 No. 333-193969) and related Prospectus of Akebia Therapeutics, Inc. for the registration of shares of its common stock.

/s/ Ernst & Young LLP

Cincinnati, Ohio  
March 3, 2014