

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

**FORM S-3  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**AKEBIA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

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

**20-8756903**  
(I.R.S Employer  
Identification No.)

**245 First Street, Suite 1100  
Cambridge, MA 02142  
(617) 871-2098**

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

**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)

*With copies to:*

**Paul M. Kinsella**  
Ropes & Gray LLP  
Prudential Tower  
800 Boylston Street  
Boston, MA 02199  
(617) 951-7000

**Nicole R. Hadas**  
Senior Vice President,  
General Counsel and Secretary  
Akebia Therapeutics, Inc.  
245 First Street, Suite 1100  
Cambridge, MA 02142  
(617) 871-2098

**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

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 as amended, or Securities Act, other than securities offered only in connection with dividend or interest reinvestment plans, 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, please 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

**CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered	Proposed maximum aggregate offering price	Amount of registration fee(1)
Common Stock, \$0.00001	\$175,000,000	\$17,623

(1) Calculated pursuant to Rule 457(o) under the Securities Act.

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, as amended, 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.

**EXPLANATORY NOTE**

This registration statement contains two prospectuses:

- a base prospectus which covers the potential future offer, issuance and sale of up to \$100,000,000 of our common stock; and
- an at-the-market offering prospectus covering the potential future offer, issuance and sale of up to \$75,000,000 of our common stock pursuant to a sales agreement with Cantor Fitzgerald & Co.

The base prospectus immediately follows this explanatory note. The at-the-market offering prospectus immediately follows the base prospectus.

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**The information in this 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 prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion, May 5, 2016**

**PROSPECTUS**

**\$100,000,000**



**Common Stock**

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We may offer and sell from time to time, in one or more series or issuances and on terms that we will determine at the time of the offering, shares of our common stock described in this prospectus, up to an aggregate amount of \$100,000,000.

We will provide specific terms of any offering in a supplement to this prospectus. Any prospectus supplement may also add, update, or change information contained in this prospectus. You should carefully read this prospectus and the applicable prospectus supplement as well as the documents incorporated or deemed to be incorporated by reference in this prospectus before you purchase any of the securities offered hereby.

These securities may be offered and sold in the same offering or in separate offerings, to or through underwriters, dealers, and agents, or directly to purchasers. The names of any underwriters, dealers, or agents involved in the sale of our securities and their compensation will be described in the applicable prospectus supplement.

Our common stock is traded on The NASDAQ Global Market under the symbol "AKBA." On May 4, 2016, the closing price of our common stock was \$9.17 per share.

**Investing in our securities involves risks. See "[Risk Factors](#)" on page 2.**

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

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**Prospectus dated \_\_\_\_\_, 2016**

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You should rely only on the information contained in, or incorporated by reference into, this prospectus. We have not authorized anyone to give you information different from that contained in this prospectus. We are not making an offer to sell these securities in any jurisdiction where the offer is not permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of when this prospectus is delivered or when any sale of our securities occurs. Our business, financial condition, results of operations and prospects may have changed since that date.

## ABOUT THIS PROSPECTUS

This prospectus is a part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a “shelf” registration process. Under this shelf registration process, we may offer to sell any combination of the securities described in this prospectus in one or more offerings up to a total dollar amount of \$175,000,000. Each time we sell securities under this shelf registration, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may also add, update or change information contained in this prospectus. You should read both this prospectus and the applicable prospectus supplement, including all documents incorporated herein by reference, together with additional information described under “Where You Can Find More Information” below.

This prospectus does not include all of the information that is in the registration statement. We omitted certain parts of the registration statement from this prospectus as permitted by the SEC. We refer you to the registration statement and its exhibits for additional information about us and the securities that may be sold under this prospectus.

We have not authorized any dealer, agent or other person to give any information or to make any representation other than those contained or incorporated by reference in this prospectus and any accompanying prospectus supplement. You must not rely upon any information or representation not contained or incorporated by reference in this prospectus or an accompanying prospectus supplement. This prospectus and the accompanying prospectus supplement, if any, do not constitute an offer to sell or the solicitation of an offer to buy any securities other than the registered securities to which they relate, nor do this prospectus and the accompanying prospectus supplement constitute an offer to sell or the solicitation of an offer to buy securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction. You should not assume that the information contained in this prospectus and the accompanying prospectus supplement, if any, is accurate on any date subsequent to the date set forth on the front of the document or that any information we have incorporated by reference is correct on any date subsequent to the date of the document incorporated by reference, even though this prospectus and any accompanying prospectus supplement is delivered or securities are sold on a later date.

“Akebia,” “we,” “us,” “our” and similar names refer to Akebia Therapeutics, Inc. unless we state otherwise or the context otherwise requires.

## ABOUT AKEBIA THERAPEUTICS, INC.

Akebia Therapeutics, Inc., or Akebia, is 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 serious unmet medical needs. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body and a potentially novel mechanism for the treatment of anemia secondary to chronic kidney disease, or CKD. Pharmacologic modulation of the HIF pathway may also have broader therapeutic applications in acute renal failure, organ protection, ischemia-reperfusion injury, cancer, ophthalmology, and inflammatory diseases.

Akebia was incorporated in 2007 under the laws of the State of Delaware. Our principal executive offices are located at 245 First Street, Suite 1100, Cambridge, MA, 02142. Our telephone number is (617) 871-2098 and our website address is [www.akebia.com](http://www.akebia.com). The information contained in, and that can be accessed through, our website is not incorporated into and does not form a part of this prospectus.

**RISK FACTORS**

*Investing in our securities involves a high degree of risk. See “Item 1A—Risk Factors” in our most recent Annual Report on Form 10-K incorporated by reference in this prospectus and in any subsequent Quarterly Report on Form 10-Q and the “Risk Factors” section in the applicable prospectus supplement for a discussion of the factors you should carefully consider before deciding to purchase our securities.*

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, any prospectus supplement and the other documents we have filed with the SEC that are incorporated herein by reference contain forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “potential,” “will,” “would,” “could,” “should,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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. In particular, you should consider the numerous risks described in our Annual Report on Form 10-K for the year ended December 31, 2015 and any subsequent Quarterly Reports on Form 10-Q, each incorporated by reference in this prospectus, and in the “Risk Factors” section in the applicable prospectus supplement (see “Where You Can Find More Information”).

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. You should not rely upon forward-looking statements as predictions of future events. Unless required by law, we will not undertake and we specifically disclaim any obligation to release publicly the result of any revisions which may be made to any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of events, whether or not anticipated. In that respect, we wish to caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made.

## USE OF PROCEEDS

Except as otherwise provided in the applicable prospectus supplement, we intend to use the net proceeds we receive from our sale of the securities covered by this prospectus for general corporate purposes, which may include working capital, capital expenditures, research and development expenditures, clinical trial expenditures, commercial expenditures, and possible acquisitions or in-licenses of product candidates. Additional information on the use of net proceeds we receive from the sale of securities covered by this prospectus may be set forth in the prospectus supplement relating to the specific offering.



## PLAN OF DISTRIBUTION

We may sell shares of common stock in any of the ways described below or in any combination:

- to or through underwriters or dealers;
- through one or more agents; or
- directly to purchasers or to a single purchaser.

The distribution of the common stock by us may be effected from time to time in one or more transactions:

- at a fixed price, or prices, which may be changed from time to time;
- at market prices prevailing at the time of sale;
- at prices related to such prevailing market prices; or
- at negotiated prices.

Each prospectus supplement will describe the method of distribution of the securities and any applicable restrictions.

The prospectus supplement will describe the terms of the offering of the securities, including the following:

- the name or names of any underwriters, dealers or agents and the amounts of securities underwritten or purchased by each of them;
- the public offering price of the securities and the proceeds to us and any discounts, commissions or concessions allowed or reallocated or paid to dealers; and
- any securities exchanges on which the securities may be listed.

Any offering price and any discounts or concessions allowed or reallocated or paid to dealers will be specified in the applicable prospectus supplement and may be changed from time to time.

Only the agents or underwriters named in each prospectus supplement are agents or underwriters in connection with the securities being offered thereby.

We may authorize underwriters, dealers or other persons acting as our agents to solicit offers by certain institutions to purchase securities from us pursuant to delayed delivery contracts providing for payment and delivery on the date stated in each applicable prospectus supplement. Each contract will be for an amount not less than, and the aggregate amount of securities sold pursuant to such contracts shall not be less nor more than, the respective amounts stated in each applicable prospectus supplement. Institutions with whom the contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutions, but shall in all cases be subject to our approval. Delayed delivery contracts will be subject only to those conditions set forth in each applicable prospectus supplement, and each prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

Agents, underwriters and other third parties described above may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution from us with respect to payments which the agents, underwriters or other third parties may be required to make in respect thereof. Agents, underwriters and such other third parties may be customers of, engage in transactions with, or perform services for us in the ordinary course of business. We may also use underwriters or such other third parties with whom we have a material relationship. We will describe the nature of any such relationship in the applicable prospectus supplement.

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One or more firms, referred to as “remarketing firms,” may also offer or sell the securities, if a prospectus supplement so indicates, in connection with a remarketing arrangement upon their purchase. Remarketing firms will act as principals for their own accounts or as our agents. These remarketing firms will offer or sell the securities in accordance with the terms of the securities. Each prospectus supplement will identify and describe any remarketing firm and the terms of its agreement, if any, with us and will describe the remarketing firm’s compensation. Remarketing firms may be deemed to be underwriters in connection with the securities they remarket. Remarketing firms may be entitled under agreements that may be entered into with us to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, and may be customers of, engage in transactions with or perform services for us in the ordinary course of business.

Certain underwriters may use this prospectus and any accompanying prospectus supplement for offers and sales related to market-making transactions in the securities. These underwriters may act as principal or agent in these transactions, and the sales will be made at prices related to prevailing market prices at the time of sale. Any underwriters involved in the sale of the securities may qualify as “underwriters” within the meaning of Section 2(a)(11) of the Securities Act. In addition, the underwriters’ commissions, discounts or concessions may qualify as underwriters’ compensation under the Securities Act and the rules of the Financial Industry Regulatory Authority.

Our common stock is listed on The NASDAQ Global Market. Underwriters may make a market in our common stock, but will not be obligated to do so and may discontinue any market making at any time without notice. We can make no assurance as to the development, maintenance or liquidity of any trading market for the securities.

Certain persons participating in an offering may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with rules and regulations under the Exchange Act. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a short covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

## DESCRIPTION OF COMMON STOCK

The following summary of the terms of our common stock does not purport to be complete. You should refer to our certificate of incorporation and bylaws, both of which are on file with the SEC as exhibits to previous filings. The summary below is also qualified by provisions of applicable law.

### 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, 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.

Our authorized capital stock consists of 175,000,000 shares of our common stock, par value \$0.00001 per share and 25,000,000 shares of undesignated preferred stock, par value \$0.00001 per share.

As of March 31, 2016, we had issued and outstanding:

- 37,946,010 shares of our common stock;
- options to purchase a total of 2,706,718 shares of our common stock with a weighted-average exercise price of \$8.98 per share; and
- 405,363 shares of our common stock reserved for issuance upon the vesting of outstanding restricted stock units.

As of March 1, 2016, we had approximately 28 holders of record of our common stock.

### 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 are 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 is 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 is 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.

### Anti-Takeover Effects of Our Certificate of Incorporation and Our Bylaws

Our certificate of incorporation and bylaws 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 our company unless such takeover or change in control is approved by the Board of Directors.

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These provisions include:

*Classified Board.* Our certificate of incorporation provides that our Board of Directors is 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 is elected each year. The classification of directors has the effect of making it more difficult for stockholders to change the composition of our Board. Our certificate of incorporation also provides that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors shall be fixed exclusively pursuant to a resolution adopted by our Board of Directors.

*Action by Written Consent; Special Meetings of Stockholders.* Our certificate of incorporation provides 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 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 are not 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 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 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 may only 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 do 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 our 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 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 our company entitled to vote with respect thereto, voting together as a single class, are 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 our company entitled to vote with respect thereto, voting together as a single class, are 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. 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 are 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

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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 provides 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**

We are 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 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**

Our common stock has been listed on The NASDAQ Global Market under the symbol "AKBA".

## WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 with the SEC for the shares of common stock offered by this prospectus. This prospectus does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information.

We are required to file annual and quarterly reports, current reports, proxy statements, and other information with the SEC. We make these documents publicly available, free of charge, on our website at [www.akebia.com](http://www.akebia.com) as soon as reasonably practicable after filing such documents with the SEC. The information contained on our website is not part of this prospectus. You can read our SEC filings, including the registration statement, on the SEC's website at <http://www.sec.gov>. You also may read and copy any document we file with the SEC at its public reference facility at:

Public Reference Room  
100 F Street N.E.  
Washington, DC 20549

Please call the SEC at 1-800-732-0330 for further information on the operation of the public reference facilities.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to “incorporate by reference” into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information in documents that we file later with the SEC will automatically update and supersede information in this prospectus. We incorporate by reference into this prospectus the documents listed below and any future filings made by us with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, except for information “furnished” under Items 2.02, 7.01 or 9.01 on Form 8-K or other information “furnished” to the SEC which is not deemed filed and not incorporated in this prospectus, until the termination of the offering described in the applicable prospectus supplement. We hereby incorporate by reference the following documents:

- our Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the SEC on March 14, 2016;
- our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2016;
- our Current Reports on Form 8-K filed on January 4, 2016, January 5, 2016 and January 12, 2016;
- our Definitive Proxy Statement, filed with the SEC on April 29, 2016; and
- Description of Common Stock, which is contained in the Registration Statement on Form 8-A, as filed with the SEC on March 12, 2014 and including any amendments or reports filed for the purpose of updating such description.

You may request a copy of these filings, at no cost, by writing or telephoning us at the following address:

Investor Relations  
Akebia Therapeutics, Inc.  
245 First Street, Suite 1100  
Cambridge, Massachusetts 02142  
(617) 871-2098

Copies of these filings are also available, without charge, on the SEC’s website at [www.sec.gov](http://www.sec.gov) and on our website at [www.akebia.com](http://www.akebia.com) as soon as reasonably practicable after they are filed electronically with the SEC. The information contained on our website is not a part of this prospectus.

## **LEGAL MATTERS**

The validity of the issuance of the common stock offered pursuant to this prospectus will be passed upon for us by Ropes & Gray LLP, Boston, Massachusetts. The validity of any securities will be passed upon for any underwriters or agents by counsel that we will name in the applicable prospectus supplement.

## **EXPERTS**

The consolidated financial statements of Akebia Therapeutics, Inc. appearing in Akebia Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2015 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.



**The information in this 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 prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

Subject to Completion, May 5, 2016

PROSPECTUS

\$75,000,000



**Common Stock**

We have entered into a sales agreement with Cantor Fitzgerald & Co. relating to shares of our common stock offered by this prospectus. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to \$75,000,000 from time to time through Cantor Fitzgerald & Co., acting as sales agent.

Our common stock is traded on The NASDAQ Global Market under the symbol "AKBA." On May 4, 2016, the last reported sale price of our common stock was \$9.17 per share.

We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and certain documents we have filed or will file with the Securities and Exchange Commission, including documents that are incorporated by reference herein.

Sales of our common stock, if any, under this prospectus may be made in sales deemed to be "at-the-market" equity offerings as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act, including sales made directly on or through The NASDAQ Global Market, the existing trading market for our common stock, sales made to or through a market maker other than on an exchange or otherwise, in negotiated transactions at market prices prevailing at the time of sale or at prices related to such prevailing market prices, and/or any other method permitted by law, including in privately negotiated transactions. Subject to the terms of the sales agreement, Cantor Fitzgerald & Co. will act as sales agent and use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between Cantor Fitzgerald & Co. and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cantor Fitzgerald & Co. will be entitled to compensation at a commission rate of up to 3.0% of the gross sales price per share sold. In connection with the sale of shares of our common stock on our behalf, Cantor Fitzgerald & Co. will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Cantor Fitzgerald & Co. will be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Cantor Fitzgerald & Co. with respect to certain liabilities pursuant to the terms of the sales agreement.

**Investing in our common stock involves a high degree of risk. Before making an investment decision, you should carefully consider all of the information set forth in this prospectus and the documents incorporated by reference herein. See "[Risk Factors](#)" on page 5 of this prospectus and under similar headings in the documents incorporated by reference into this prospectus.**

*Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.*



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You should rely only on the information contained in, or incorporated by reference into, this prospectus. We have not authorized anyone to give you information different from that contained in this prospectus. We are not making an offer to sell these securities in any jurisdiction where the offer is not permitted. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of when this prospectus is delivered or when any sale of our securities occurs. Our business, financial condition, results of operations and prospects may have changed since that date.

## ABOUT THIS PROSPECTUS

This prospectus relates to part of a registration statement that we have filed with the Securities and Exchange Commission, or SEC, utilizing a “shelf” registration process. The \$75,000,000 of common stock that may be offered, issued and sold under this prospectus is included in the \$175,000,000 of securities that may be offered, issued and sold by us pursuant to our shelf registration statement.

This prospectus includes or incorporates by reference important information about us, our common stock, and other matters you should know before investing. You should read this prospectus as well as additional information described under “Where You Can Find More Information” before making an investment decision.

You should rely only on this prospectus and the information incorporated or deemed to be incorporated by reference in this prospectus or in any free writing prospectuses we provide you. We have not, and Cantor Fitzgerald has not, authorized anyone to provide you with information that is in addition to, or different from, that contained or incorporated by reference in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and Cantor Fitzgerald is not, offering to sell securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained or incorporated by reference in this prospectus is accurate as of any date other than as of the date of this prospectus or in the case of the documents incorporated by reference, the date of such documents regardless of the time of delivery of this prospectus or any sale of our common shares. Our business, financial condition, liquidity, results of operations, and prospects may have changed since those dates.

Unless stated otherwise or the context otherwise requires, we use the terms “Akebia,” “Akebia Therapeutics,” “we,” “us,” “the company” and “our” in this prospectus to refer to Akebia Therapeutics, Inc. and its subsidiaries. When we refer to “you” or “yours” we mean the investors and potential investors in the shares of common stock offered hereby.

## PROSPECTUS SUMMARY

*This summary highlights selected information included or incorporated by reference in this prospectus and the documents incorporated by reference herein, and does not contain all of the information that may be important to you. You should carefully review this entire prospectus and the documents incorporated by reference, including the risk factors and financial statements included and incorporated by reference in this prospectus, before making your investment decision.*

### **Our Business**

Akebia Therapeutics, Inc., or Akebia, is 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 serious unmet medical needs. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body and a potentially novel mechanism for the treatment of anemia secondary to chronic kidney disease, or CKD. Pharmacologic modulation of the HIF pathway may also have broader therapeutic applications in acute renal failure, organ protection, ischemia-reperfusion injury, cancer, ophthalmology, and inflammatory diseases.

Akebia was incorporated in 2007 under the laws of the State of Delaware. Our principal executive offices are located at 245 First Street, Suite 1100, Cambridge, MA, 02142. Our telephone number is (617) 871-2098 and our website address is [www.akebia.com](http://www.akebia.com). The information contained in, and that can be accessed through, our website is not incorporated into and does not form a part of this prospectus.

## THE OFFERING

*The following summary contains basic information about our common stock and the offering and is not intended to be complete. It does not contain all the information that may be important to you. For a more complete understanding of our common stock, you should read this prospectus and the documents referred to herein.*

Issuer	Akebia Therapeutics, Inc.
Common stock offered by us	Shares of our common stock having an aggregate offering price of up to \$75,000,000.
Common stock to be outstanding after this offering	Up to 45,446,010 shares (as more fully described in the notes following this table), assuming sales of 7,500,000 shares of our common stock in this offering at an assumed public offering price of \$10.00 per share. The actual number of shares issued in connection with this offering will vary depending on how many shares of our common stock we choose to sell and the prices at which such sales occur.
Manner of offering	Sales of shares of our common stock under this prospectus may be made by any method deemed to be an “at the market” offering as defined in Rule 415 under the Securities Act of 1933, as amended, which includes sales made directly on The NASDAQ Global Market, the existing trading market for our common stock, or sales made to or through a market maker other than on an exchange. Sales may also be made in privately negotiated transactions and/or any other method permitted by law. Subject to the terms of the sales agreement, Cantor Fitzgerald & Co. will make all sales using commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The NASDAQ Global Market, on mutually agreeable terms between Cantor Fitzgerald & Co. and us. See “Plan of Distribution” beginning on page 14 of this prospectus.
Sales agent	Cantor Fitzgerald & Co.
Use of proceeds	We expect to use the net proceeds from this offering, if any, (i) for clinical development of our lead product candidate, and discovery, research and preclinical studies of our other product candidates; and (ii) to fund working capital, capital expenditures and other general corporate purposes, which may include the acquisition or in-license of additional compounds, product candidates or technology. See “Use of Proceeds” beginning on page 6 of this prospectus.
Risk factors	Your investment in shares of our common stock involves substantial risks. You should consider the matters referred to under the heading “Risk Factors” in this prospectus, including the risk factors incorporated by reference herein and therein from our filings with the SEC.
NASDAQ Global Market symbol	“AKBA.”

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The number of shares of common stock shown above to be outstanding after this offering is based on 37,946,010 shares of our common stock outstanding as of March 31, 2016, including 189,273 shares of unvested restricted stock subject to repurchase by us, and excluding:

- 2,706,718 shares of our common stock reserved for issuance upon the exercise of outstanding stock options at a weighted average exercise price of \$8.98 per share;
- 405,363 shares of our common stock reserved for issuance upon the vesting of outstanding restricted stock units; and
- 2,210,452 shares of our common stock reserved for future awards under our 2014 Incentive Plan.

## RISK FACTORS

*An investment in our common stock involves risks. You should carefully consider the risks described below, as well as the other information included or incorporated by reference in this prospectus, including “Part I, Item 1A—Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 14, 2016, and in any subsequent Quarterly Reports on Form 10-Q, before making an investment decision. In addition, please read “About this Prospectus” in this prospectus and “Cautionary Note Regarding Forward-Looking Statements” in this prospectus, where we describe additional uncertainties associated with our business and the forward-looking statements included or incorporated by reference in this prospectus. Please note that additional risks not currently known to us or that we currently deem immaterial may also impair our business and operations.*

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

The assumed offering price per share of our common stock in this offering is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. Assuming the sale of \$75,000,000 of our common stock in this offering, based on the assumed offering price of \$10.00 per share, and net tangible book value per share of our common stock of \$4.42 as of March 31, 2016, if you purchase shares in this offering, you will suffer immediate and substantial dilution of \$4.70 per share in the as adjusted net tangible book value of common stock purchased. See “Dilution” beginning on page 8 of this prospectus for a more detailed description of the dilution to new investors in this offering.

***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, if any, from this offering for clinical development of our lead product candidate, discovery, research and preclinical studies of our other product candidates and to fund working capital, capital expenditures and other general corporate purposes, which may include the acquisition or in-license of additional compounds, product candidates or technology. See “Use of Proceeds” beginning on page 6 of this prospectus for further detail. Although we currently intend to use the net proceeds, if any, from this offering in such a manner, we will have broad discretion in the application of such 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.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the other documents we have filed with the SEC that are incorporated herein by reference contain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Exchange Act, which involve substantial risks and uncertainties. All statements, other than statements of historical facts, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “potential,” “will,” “would,” “should,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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. In particular, you should consider the numerous risks described in the “Risk Factors” section in this prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2015 and any subsequent Quarterly Reports on Form 10-Q, each incorporated by reference in this prospectus (see “Where You Can Find More Information”).

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. You should not rely upon forward-looking statements as predictions of future events. Unless required by law, we will not undertake and we specifically disclaim any obligation to release publicly the result of any revisions which may be made to any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of events, whether or not anticipated. In that respect, we wish to caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made.

## USE OF PROCEEDS

We may issue and sell shares of our common stock having aggregate gross sales proceeds of up to \$75,000,000 from time to time under this prospectus. Because there is no minimum offering amount required pursuant to the sales agreement with Cantor Fitzgerald & Co., the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. Actual net proceeds will depend on the number of shares we sell and the prices at which such sales occur. There can be no assurance that we will sell any shares under or fully utilize the sales agreement with Cantor Fitzgerald & Co. as a source of financing.

We intend to use the net proceeds, if any, from sales of shares of our common stock covered by this prospectus as follows:

- for clinical development of our lead product candidate, and discovery, research and preclinical studies of our other product candidates; and
- the balance to fund working capital, capital expenditures and other general corporate purposes, which may include the acquisition or in-license of additional compounds, product candidates or technology.

Our expected use of net proceeds, if any, from the sale of shares of common stock pursuant to the sales agreement with Cantor Fitzgerald & Co. 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



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authorities. As a result, our management will have broad discretion over the use of the net proceeds from this offering, if any. We may temporarily invest the net proceeds in investment-grade, interest-bearing securities pending their use for the purposes described above. We have not determined the amount of net proceeds to be used specifically for such purposes and, as a result, management will retain broad discretion over the allocation of net proceeds, if any.

**DIVIDEND POLICY**

We have not paid cash dividends on our common stock during our two most recent fiscal years. We do not intend to pay any dividends on our common stock for the foreseeable future.

## PRICE RANGE OF OUR COMMON STOCK

Our common stock has been listed on The NASDAQ Global Market under the symbol “AKBA” since our initial public offering on March 19, 2014. The following table summarizes the high and low sale prices per share for our common stock for the fiscal periods indicated as reported on The NASDAQ Global Market.

	<u>High</u>	<u>Low</u>
<b>2014</b>		
First Quarter from and after March 20th	\$28.50	\$18.75
Second Quarter	\$31.00	\$16.41
Third Quarter	\$28.33	\$20.10
Fourth Quarter	\$21.75	\$ 8.60
<b>2015</b>		
First Quarter	\$13.90	\$ 8.47
Second Quarter	\$11.12	\$ 7.27
Third Quarter	\$14.20	\$ 5.91
Fourth Quarter	\$13.20	\$ 7.91
<b>2016</b>		
First Quarter	\$12.74	\$ 7.02
Second Quarter (through May 4, 2016)	\$ 9.99	\$ 8.78

On May 4, 2016, the last reported sale price for our common stock on The NASDAQ Global Market was \$9.17 per share. As of March 1, 2016, we had approximately 28 holders of record of our common stock.

## DILUTION

If you invest in our common stock, your interest will be diluted to the extent of the difference between the price per share you pay in this offering and the net tangible book value per share of our common stock immediately after this offering. Our net tangible book value of our common stock as of March 31, 2016 was approximately \$167.8 million, or approximately \$4.42 per share of common stock based upon 37,946,010 shares outstanding as of March 31, 2016. Net tangible book value per share is equal to our total tangible assets, less our total liabilities, divided by the total number of shares outstanding as of March 31, 2016.

After giving effect to the assumed sale of 7,500,000 shares of common stock by us in this offering at the assumed public offering price of \$10.00 per share, less the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2016 would have been \$241.0 million, or \$5.30 per share. This represents an immediate increase in net tangible book value per share of \$0.88 to existing stockholders and immediate dilution of \$4.70 in net tangible book value per share to new investors purchasing common stock in this offering.

Assumed public offering price per share	\$10.00
Net tangible book value per share as of March 31, 2016	\$4.42
Increase in net tangible book value per share attributable to the offering	<u>0.88</u>
As adjusted net tangible book value per share after giving effect to the offering	<u>5.30</u>
Dilution in net tangible book value per share to new investors in the offering	<u>4.70</u>

The foregoing table is based on 37,946,010 shares of our common stock outstanding and excludes the following, each as of March 31, 2016:

- 2,706,718 shares of our common stock reserved for issuance upon the exercise of outstanding stock options at a weighted average exercise price of \$8.98 per share;
- 405,363 shares of our common stock reserved for issuance upon the vesting of outstanding restricted stock units; and
- 2,210,452 shares of our common stock reserved for future awards under our 2014 Incentive Plan.

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Each \$1.00 increase (decrease) in the assumed public offering price of \$10.00 per share, assuming all of the common stock we are offering, in the aggregate amount of \$75,000,000, is sold at that price per share, would increase (decrease) our as adjusted net tangible book value per share after this offering by approximately \$0.08 per share, and the dilution per share to new investors by approximately \$0.92 per share, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. The information discussed above is illustrative only and will adjust based on the actual number of shares that are sold in this offering and the prices at which such sales are made.

## 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 U.S. Internal Revenue Code of 1986, as amended, or 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 have not paid cash dividends on our common stock during our two most recent fiscal years and 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 W-8BEN-E (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.

With respect to the third exception, if a Non-U.S. Holder is engaged in a trade or business in the U.S. and gain recognized by the Non-U.S. Holder on a sale or other disposition of our common stock is effectively connected with the conduct of such trade or business, the Non-U.S. Holder will generally be subject to regular U.S. income tax as if the Non-U.S. Holder were a U.S. person, subject to an applicable income tax treaty providing otherwise. Additionally, a non-U.S. corporation may also, under certain circumstances, be subject to an additional “branch profits tax” imposed at a rate of 30% (or, if applicable, a lower income tax treaty rate). Non-U.S. Holders whose gain from dispositions of our common stock may be effectively connected with the conduct of a trade or business in the United States are urged to consult their tax advisors with respect to the U.S. tax consequences of the purchase, ownership and disposition of our common stock.

## **Additional Withholding and Reporting Requirements**

Sections 1471 through 1474 of the Code and related Treasury Regulations (commonly referred to as “FATCA”) generally will impose a U.S. federal withholding tax of 30% on payments to certain non-U.S. entities

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(including certain intermediaries), including dividends on and the gross proceeds from a sale or other disposition of shares of our common stock, unless such persons comply with a complicated U.S. information reporting, disclosure and certification regime. This new regime requires, among other things, a broad class of persons to enter into agreements with the IRS to obtain, disclose and report information about their investors and account holders. An intergovernmental agreement between the United States and an applicable foreign country may, however, modify these requirements. The FATCA withholding rules currently apply to dividend payments on our common stock and will apply to payments of gross proceeds from the sale or other disposition of shares of our common stock occurring after December 31, 2016. Prospective investors should consult their own tax advisors regarding the possible impact of these rules on their investment in our common stock, and the possible impact of these rules on 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.

## PLAN OF DISTRIBUTION

We have entered into a Controlled Equity Offering<sup>SM</sup> sales agreement with Cantor Fitzgerald & Co., or Cantor, under which we may issue and sell shares of our common stock having an aggregate gross sales price of up to \$75,000,000 from time to time through Cantor acting as agent. The sales agreement has been filed as an exhibit to our registration statement on Form S-3 of which this prospectus forms a part.

Upon delivery of a placement notice and subject to the terms and conditions of the sales agreement, Cantor may sell shares of our common stock by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act, including sales made directly on The NASDAQ Global Market, on any other existing trading market for our common stock or to or through a market maker. Cantor may also sell our common stock by any other method permitted by law, including in privately negotiated transactions. We may instruct Cantor not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or Cantor may suspend the offering of common stock upon notice and subject to other conditions.

We will pay Cantor commissions, in cash, for its services in acting as agent in the sale of our common stock. Cantor will be entitled to compensation at a commission rate of up to 3.0% of the gross sales price per share sold. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have also agreed to reimburse Cantor for certain specified expenses, including the fees and disbursements of its legal counsel in an amount not to exceed \$50,000. We estimate that the total expenses for the offering, excluding compensation and reimbursements payable to Cantor under the terms of the sales agreement, will be approximately \$215,000.

Settlement for sales of shares of common stock will occur on the third business day following the date on which any sales are made, or on some other date that is agreed upon by us and Cantor in connection with a particular transaction, in return for payment of the net proceeds to us. Sales of our common stock as contemplated in this prospectus will be settled through the facilities of The Depository Trust Company or by such other means as we and Cantor may agree upon. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

Cantor will use its commercially reasonable efforts, consistent with its sales and trading practices, to solicit offers to purchase the shares of common stock under the terms and subject to the conditions set forth in the sales agreement. In connection with the sale of the shares of common stock on our behalf, Cantor will be deemed to be an “underwriter” within the meaning of the Securities Act and the compensation of Cantor will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Cantor against certain civil liabilities, including liabilities under the Securities Act.

The offering of shares of our common stock pursuant to the sales agreement will terminate upon the earlier of (i) the sale of all the shares of our common stock that are subject to the sales agreement having an aggregate offering price of \$75,000,000, or (ii) termination of the sales agreement as permitted therein.

Cantor and its affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Cantor will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

This prospectus in electronic format may be made available on a website maintained by Cantor and Cantor may distribute this prospectus electronically.



## LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Ropes & Gray LLP, Boston, Massachusetts. Certain legal matters will be passed upon for Cantor Fitzgerald & Co. by Latham & Watkins LLP, San Diego, California.

## EXPERTS

The consolidated financial statements of Akebia Therapeutics, Inc. appearing in Akebia Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2015 have been audited by Ernst & Young LLP, independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference 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 a registration statement on Form S-3 with the SEC for the shares of common stock offered by this prospectus. This prospectus, including the information incorporated by reference, does not include all of the information contained in the registration statement. You should refer to the registration statement and its exhibits for additional information.

We are required to file annual and quarterly reports, current reports, proxy statements, and other information with the SEC. We make these documents publicly available, free of charge, on our website at [www.akebia.com](http://www.akebia.com) as soon as reasonably practicable after filing such documents with the SEC. The information contained on our website is not part of this prospectus. You can read our SEC filings, including the registration statement, on the SEC's website at <http://www.sec.gov>. You also may read and copy any document we file with the SEC at its public reference facility at:

Public Reference Room  
100 F Street N.E.  
Washington, DC 20549

Please call the SEC at 1-800-732-0330 for further information on the operation of the public reference facilities.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

We incorporate by reference in this prospectus the documents listed below and any future filings we make with the Securities and Exchange Commission, or the SEC, under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (in each case, other than those documents or the portions of those documents not deemed to be filed) until the termination of the offering of the shares of common stock to which this prospectus relates. Any statement in a document incorporated by reference is an important part of this prospectus. Any statement in a document incorporated by reference in this prospectus will be deemed to be modified or superseded to the extent a statement contained in this prospectus or any subsequently filed document that is incorporated by reference in this prospectus modifies or supersedes such statement.

We incorporate by reference in this prospectus only the documents set forth below that have been previously filed with the SEC:

- our Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 14, 2016;

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- our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2016;
- our Current Reports on Form 8-K filed on January 4, 2016, January 5, 2016 and January 12, 2016;
- our Definitive Proxy Statement, filed with the SEC on April 29, 2016; and
- Description of Capital Stock, which is contained in the Registration Statement on Form 8-A, as filed with the SEC on March 12, 2014.

We will provide without charge to each person to whom a copy of this prospectus is delivered, upon the written or oral request of such person, a copy of any or all of the documents incorporated by reference (other than exhibits to those documents, unless the exhibits are specifically incorporated by reference into those documents). Requests should be directed to Investor Relations, Akebia Therapeutics, Inc., 245 First Street, Suite 1100, Cambridge, Massachusetts 02142 or may be made by phone by calling (617) 871-2098.

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 14. Other Expenses of Issuance and Distribution.**

The following table sets forth the various expenses in connection with the sale and distribution of the securities being registered.

Securities and Exchange Commission Registration Fee	\$17,623
FINRA Fees	\$26,750
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer Agent and Registrar fees	*
Miscellaneous	*
Total	*

\* These fees are calculated based on the number of issuances and the amount of securities offered and accordingly cannot be estimated at this time.

**Item 15. Indemnification of Directors and Officers.**

The registrant's certificate of incorporation contains provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, the personal liability of directors and executive officers for monetary damages for breach of their fiduciary duties as a director or officer. The registrant's certificate of incorporation and bylaws provide that the registrant shall indemnify its directors and executive officers and may indemnify its employees and other agents to the fullest extent permitted by the General Corporation Law of the State of Delaware.

Sections 145 and 102(b)(7) of the General Corporation Law of the State of Delaware provide that a corporation may indemnify any person made a party to an action by reason of the fact that he or she was a director, executive officer, employee or agent of the corporation or is or was serving at the request of the corporation against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action if he or she 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 corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful, except that, in the case of an action by or in right of the corporation, no indemnification may generally be made in respect of any claim as to which such person is adjudged to be liable to the corporation.

The registrant has entered into indemnification agreements with each of its directors and executive officers, in addition to the indemnification provided for in the registrant's amended and restated certificate of incorporation and bylaws, and intends to enter into indemnification agreements with any new directors and executive officers in the future.

The registrant maintains insurance on behalf of any person who is or was a director or officer of the registrant against any loss arising from any claim asserted against him or her and incurred by him or her in any such capacity, subject to certain exclusions.

**Item 16. Exhibits**

See Exhibit Index at the end of this registration statement.

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### **Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

*Provided, however, that*

Paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
  - (A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
  - (B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration

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statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424; (ii) any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant; (iii) the portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and (iv) any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (6) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement 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.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 Securities Act of 1933 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 Securities Act, and will be governed by the final adjudication of such issue.



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/s/ Ronald C. Renaud, Jr.  
Ronald C. Renaud, Jr.

Director

May 5, 2016

/s/ Michael S. Wyzga  
Michael S. Wyzga

Director

May 5, 2016

**EXHIBIT INDEX**

The following is a list of exhibits filed as part of this registration statement.

<b>Exhibit</b>	<b>Description</b>
1.1	Form of Controlled Equity Offering <sup>SM</sup> Sales Agreement, by and between Akebia Therapeutics, Inc. and Cantor Fitzgerald & Co.
4.1	Form of Common Stock Certificate (incorporated by reference to exhibit 4.1 to the Company's Registration Statement on Form S-1/A (333-193969), filed on March 4, 2014)
4.2	Fourth Amended and Restated Investors' Rights Agreement, dated March 5, 2014 (incorporated by reference to exhibit 4.4 to the Company's 10-K for the year ending December 31, 2014 and filed on March 4, 2015)
5.1	Opinion of Ropes & Gray LLP
5.2	Opinion of Ropes & Gray LLP
23.1	Consent of Ropes & Gray LLP (included in Exhibit 5.1)
23.2	Consent of Ernst & Young LLP
24.1	Power of attorney (included on the signature page)



## AKEBIA THERAPEUTICS, INC.

Shares of Common Stock  
(par value \$0.00001 per share)

Controlled Equity Offering<sup>SM</sup>Sales Agreement

[●], 2016

Cantor Fitzgerald & Co.  
499 Park Avenue  
New York, NY 10022

Ladies and Gentlemen:

Akebia Therapeutics, Inc., a Delaware corporation (the “**Company**”), confirms its agreement (this “**Agreement**”) with Cantor Fitzgerald & Co. (the “**Agent**”), as follows:

1. **Issuance and Sale of Shares.** The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through the Agent up to \$75,000,000 of shares of common stock (the “**Placement Shares**”) of the Company, par value \$0.00001 per share (the “**Common Stock**”); *provided, however*, that in no event shall the Company issue or sell through the Agent such number or dollar amount of Placement Shares that would (a) exceed the number or dollar amount of shares of Common Stock registered on the effective Registration Statement (defined below) pursuant to which the offering is being made, (b) exceed the number of authorized but unissued shares of Common Stock, (c) exceed the number or dollar amount of shares of Common Stock permitted to be sold under Form S-3 (including Instruction I.B.6. thereof, if applicable) or (d) exceed the dollar amount of shares of Common Stock for which the Company has filed a Prospectus (defined below) (the lesser of (a), (b), (c) and (d), the “**Maximum Amount**”). Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitations set forth in this Section 1 on the amount of Placement Shares issued and sold under this Agreement shall be the sole responsibility of the Company and that, other than as set forth in this Agreement, the Agent shall have no obligation in connection with such compliance. The issuance and sale of Placement Shares through Agent will be effected pursuant to the Company’s Registration Statement, which was declared effective by the Securities and Exchange Commission (the “**Commission**”) on [●], 2016 (File No. 333-[●]), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement to issue Common Stock.

The Company has filed or will file, in accordance with the provisions of the Securities Act of 1933, as amended (the “**Securities Act**”) and the rules and regulations thereunder (the “**Securities Act Regulations**”), with the Commission a registration statement on Form S-3 (333-[●]), including a base prospectus, relating to the Placement Shares to be issued from time to time by the Company (the “**Base Prospectus**”), and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities

Exchange Act of 1934, as amended (the “**Exchange Act**”), and the rules and regulations thereunder The Company will furnish to the Agent, for use by the Agent, copies of the Base Prospectus, as supplemented by any prospectus supplement relating to the Placement Shares to be issued from time to time by the Company. The Company may file one or more additional registration statements from time to time that may contain one or more base prospectuses with respect to the Placement Shares. Except where the context otherwise requires, such registration statement(s), including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act Regulations or deemed to be a part of such registration statement pursuant to Rule 430B of the Securities Act Regulations, is herein called the “**Registration Statement**.” The Base Prospectus or base prospectuses, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented, if necessary, by any prospectus supplement, in the form in which such prospectus or prospectuses and/or prospectus supplement have most recently been filed by the Company with the Commission pursuant to Rule 424(b) under the Securities Act Regulations, together with the then issued Issuer Free Writing Prospectus(es), is herein called the “**Prospectus**.”

Any reference herein to the Registration Statement, the Base Prospectus any prospectus supplement, Prospectus or any Issuer Free Writing Prospectus (defined below) shall be deemed to refer to and include the documents, if any, incorporated by reference therein (the “**Incorporated Documents**”), including, unless the context otherwise requires, the documents, if any, filed as exhibits to such Incorporated Documents. Any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement, the Base Prospectus, any prospectus supplement, the Prospectus or any Issuer Free Writing Prospectus shall be deemed to refer to and include the filing of any document under the Exchange Act on or after the most-recent effective date of the Registration Statement, or the date of the Prospectus or such Issuer Free Writing Prospectus, as the case may be, and incorporated therein by reference. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include the most recent copy filed with the Commission pursuant to its Electronic Data Gathering Analysis and Retrieval System, or if applicable, the Interactive Data Electronic Application system when used by the Commission (collectively, “**EDGAR**”).

2. **Placements.** Each time that the Company wishes to issue and sell Placement Shares hereunder (each, a “**Placement**”), it will notify the Agent by email notice (or other method mutually agreed to in writing by the parties) of the number of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one day and any minimum price below which sales may not be made (a “**Placement Notice**”), the form of which is attached hereto as Schedule 1. The Placement Notice shall originate from any of the individuals from the Company set forth on Schedule 3 (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from the Agent set forth on Schedule 3, as such Schedule 3 may be amended from time to time. The Placement Notice shall be effective unless and until (i) the Agent declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares thereunder have been sold, (iii) the Company suspends or terminates the Placement Notice or (iv) this Agreement has

been terminated under the provisions of Section 13. The amount of any discount, commission or other compensation to be paid by the Company to Agent in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in Schedule 2. It is expressly acknowledged and agreed that neither the Company nor the Agent will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to the Agent and the Agent does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by Agent. Subject to the provisions of Section 5(a), the Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the NASDAQ Global Market (the “**Exchange**”), to sell the Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. The Agent will provide written confirmation to the Company no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the compensation payable by the Company to the Agent pursuant to Section 2 with respect to such sales, and the Net Proceeds (as defined below) payable to the Company, with an itemization of the deductions made by the Agent (as set forth in Section 5(b)) from the gross proceeds that it receives from such sales. Subject to the terms of the Placement Notice, the Agent may sell Placement Shares by any method permitted by law deemed to be an “at the market” offering as defined in Rule 415 of the Securities Act Regulations, including without limitation sales made directly on the Exchange, on any other existing trading market for the Common Stock or to or through a market maker. Subject to the terms of a Placement Notice, the Agent may also sell Placement Shares by any other method permitted by law, including but not limited to in privately negotiated transactions. “**Trading Day**” means any day on which Common Stock is traded on the Exchange.

4. Suspension of Sales. The Company or the Agent may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on Schedule 3, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on Schedule 3), suspend any sale of Placement Shares (a “**Suspension**”); provided, however, that such Suspension shall not affect or impair any party’s obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a Suspension is in effect any obligation under Sections 7(l), 7(m), and 7(n) with respect to the delivery of certificates, opinions, or comfort letters to the Agent, shall be waived, provided, however, that such waiver shall not apply for the Representation Date (defined below) occurring on the date that the Company files its annual report on Form 10-K. Each of the parties agrees that no such notice under this Section 4 shall be effective against any other party unless it is made to one of the individuals named on Schedule 3 hereto, as such Schedule may be amended from time to time.

## 5. Sale and Delivery to the Agent; Settlement.

(a) Sale of Placement Shares. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, upon the Agent's acceptance of the terms of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, the Agent, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Placement Shares up to the amount specified, and otherwise in accordance with the terms of such Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that the Agent will be successful in selling Placement Shares, (ii) the Agent will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by the Agent to use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable law and regulations to sell such Placement Shares as required under this Agreement and (iii) the Agent shall be under no obligation to purchase Placement Shares on a principal basis pursuant to this Agreement, except as otherwise agreed by the Agent and the Company.

(b) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the third (3<sup>rd</sup>) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a "**Settlement Date**"). The Agent shall notify the Company of each sale of Placement Shares on the date of such sale. The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the "**Net Proceeds**") will be equal to the aggregate sales price received by the Agent, after deduction for (i) the Agent's commission, discount or other compensation for such sales payable by the Company pursuant to Section 2 hereof, and (ii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

(c) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting the Agent's or its designee's account (provided the Agent shall have given the Company written notice of such designee at least one Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradable, transferable, registered shares in good deliverable form. On each Settlement Date, the Agent will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver Placement Shares on a Settlement Date, in addition to and in no way limiting the rights and obligations set forth in Section 11(a) hereto, it will (i) hold the Agent harmless against any loss, claim, damage, or expense (including reasonable legal fees and expenses), as incurred, arising out of or in connection with such default by the Company or its transfer agent (if applicable) and (ii) pay to the Agent any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

(d) Limitations on Offering Size. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares if, after giving effect to the sale of such Placement Shares, the aggregate gross sales proceeds of Placement Shares sold pursuant to this Agreement would exceed the lesser of (A) together with all sales of Placement Shares under this Agreement, the Maximum Amount, (B) the amount available for offer and sale under the currently effective Registration Statement and (C) the amount authorized from time to time to be issued and sold under this Agreement by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Agent in writing. Under no circumstances shall the Company cause or request the offer or sale of any Placement Shares pursuant to this Agreement at a price lower than the minimum price authorized from time to time by the Company's board of directors, a duly authorized committee thereof or a duly authorized executive committee, and notified to the Agent in writing.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with Agent that as of the date of this Agreement and as of each Applicable Time (as defined below):

(a) Registration Statement and Prospectus. The Company and the transactions contemplated by this Agreement meet the requirements for and comply with the conditions for the use of Form S-3 under the Securities Act. The Registration Statement has been filed or will be filed with the Commission and has been or will be declared effective by the Commission under the Securities Act prior to the issuance of any Placement Notices by the Company. The Base Prospectus will name the Agent as the agent in the section entitled "Plan of Distribution." The Company has not received, and has no notice of, any order of the Commission preventing or suspending the use of the Registration Statement, or threatening or instituting proceedings for that purpose. The Registration Statement and the offer and sale of Placement Shares as contemplated hereby meet the requirements of Rule 415 under the Securities Act and comply in all material respects with said Rule. Any 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 have been so described or filed. Copies of the Registration Statement, the Prospectus, and any such amendments or supplements and all Incorporated Documents that were filed with the Commission on or prior to the date of this Agreement have been delivered, or are available through EDGAR, to the Agent and its counsel. The Company has not distributed and, prior to the later to occur of each Settlement Date and completion of the distribution of the Placement Shares, will not distribute any offering material in connection with the offering or sale of the Placement Shares other than the Registration Statement and the Prospectus and any Issuer Free Writing Prospectus (as defined below) to which the Agent has consented. The Common Stock is registered pursuant to Section 12(b) of the Exchange Act and is currently listed on the Exchange under the trading symbol "AKBA." The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act, delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or the Exchange is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of the Exchange.

(b) No Misstatement or Omission. The Registration Statement, when it became or becomes effective, did not, and will not, contain an 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. The Prospectus and any amendment and supplement thereto, on the date thereof and at each Applicable Time (defined below), did not or will not include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The Incorporated Documents did not, and any further Incorporated Documents filed after the date of this Agreement will not, when filed with the Commission, contain an untrue statement of a material fact or omit to state a material fact required to be stated in such document or necessary to make the statements in such document, in light of the circumstances under which they were made, not misleading. The foregoing shall not apply to statements in, or omissions from, any such document made in reliance upon, and in conformity with, information furnished to the Company by Agent specifically for use in the preparation thereof.

(c) Conformity with Securities Act and Exchange Act. The Registration Statement, the Prospectus, any Issuer Free Writing Prospectus or any amendment or supplement thereto, and the Incorporated Documents, when such documents were or are filed with the Commission under the Securities Act or the Exchange Act or became or become effective under the Securities Act, as the case may be, conformed or will conform in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable. At each Settlement Date, the Registration Statement and the Prospectus, as amended as of such date, will conform in all material respects with the requirements of the Securities Act.

(d) Financial Information. The consolidated financial statements of the Company included or incorporated by reference in the Registration Statement and the Prospectus, together with the related notes and schedules, present fairly, in all material respects, the consolidated financial position of the Company and the Subsidiaries (as defined below) as of the dates indicated and the consolidated results of operations, cash flows and changes in stockholders' equity of the Company for the periods specified (subject to normal year-end audit adjustments for interim financial statements) and have been prepared in compliance with the requirements of the Securities Act and Exchange Act and in conformity with GAAP (as defined below) applied on a consistent basis during the periods involved; the other financial and statistical data with respect to the Company and the Subsidiaries (as defined below) contained or incorporated by reference in the Registration Statement, the Prospectus and the Issuer Free Writing Prospectuses, if any, are accurately and fairly presented in all material respects and prepared on a basis consistent, in all material respects, with the financial statements and books and records of the Company; there are no financial statements (historical or pro forma) that are required to be included or incorporated by reference in the Registration Statement, or the Prospectus that are not included or incorporated by reference as required; the Company and the Subsidiaries (as defined below) do not have any material liabilities or obligations, direct or contingent (including any off-balance sheet obligations), not described in the Registration Statement (excluding the exhibits thereto), and the Prospectus; and all disclosures contained or incorporated by reference in the Registration Statement, the Prospectus and the Issuer Free Writing Prospectuses, if any, regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) comply with Regulation G of the Exchange Act and Item 10 of Regulation S-K under the Securities Act, to the extent applicable.

(e) Conformity with EDGAR Filing. The Prospectus delivered to the Agent for use in connection with the sale of the Placement Shares pursuant to this Agreement will be identical to the versions of the Prospectus created to be transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

(f) Organization. The Company and the Subsidiaries (as defined below) are, and will be, duly organized, validly existing as a corporation and in good standing under the laws of their respective jurisdictions of organization. The Company and the Subsidiaries (as defined below) are each duly licensed or qualified as a foreign corporation for transaction of business and in good standing under the laws of each other jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such license or qualification, and have all corporate power and authority necessary to own or hold their respective properties and to conduct their respective businesses as described in the Registration Statement and the Prospectus, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, have a material adverse effect on or affecting the assets, business, operations, earnings, properties, condition (financial or otherwise), stockholders' equity or results of operations of the Company and the Subsidiaries (as defined below) taken as a whole, or prevent or materially interfere with consummation of the transactions contemplated hereby (a "**Material Adverse Effect**").

(g) Subsidiaries. The subsidiaries set forth on Schedule 4 (the "**Subsidiaries**") are the only subsidiaries of the Company. The Company has no significant subsidiaries (as such term is defined in Rule 1-02 of Regulation S-X promulgated by the Commission) other than as indicated as such on Schedule 4. The Company owns, directly or indirectly, all of the equity interests of the Subsidiaries free and clear of any lien, charge, security interest, encumbrance, right of first refusal or other restriction, and all the equity interests of the Subsidiaries are validly issued and are fully paid, nonassessable and free of preemptive and similar rights.

(h) No Violation or Default. Neither the Company nor its Subsidiaries are (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or its Subsidiaries are a party or by which the Company or its Subsidiaries are bound or to which any of the property or assets of the Company or its Subsidiaries are subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of each of clauses (ii) and (iii) above, for any such violation or default that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, no other party under any material contract or other agreement to which it or its Subsidiaries are a party is in default in any respect thereunder where such default would have a Material Adverse Effect.

(i) No Material Adverse Change. Subsequent to the respective dates as of which information is given in the Registration Statement and the Prospectus and the Free Writing Prospectuses, if any, there has not been (i) any Material Adverse Effect or the occurrence of any development that the Company reasonably expects will result in a Material Adverse Effect, (ii) any transaction which is material to the Company and its Subsidiaries taken as a whole, (iii) any

obligation or liability, direct or contingent (including any off-balance sheet obligations), incurred by the Company or its Subsidiaries, which is material to the Company and its Subsidiaries taken as a whole, (iv) any material change in the capital stock or outstanding long-term indebtedness of the Company or its Subsidiaries (other than (a) as a result of the sale of Placement Shares, (b) the issuance of equity awards under the Company's existing equity incentive plans or (c) changes in the number of shares of outstanding Common Stock of the Company due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, shares of Common Stock (including warrants) outstanding on the date hereof, or the vesting of restricted stock units outstanding on the date hereof) or (v) any dividend or distribution of any kind declared, paid or made on the capital stock of the Company or the Subsidiaries, other than in each case above in the ordinary course of business or as otherwise disclosed in the Registration Statement or Prospectus (including any document deemed incorporated by reference therein).

(j) Capitalization. The issued and outstanding shares of capital stock of the Company have been validly issued, are fully paid and nonassessable and, other than as disclosed in the Registration Statement or the Prospectus, are not subject to any preemptive rights, rights of first refusal or similar rights. The Company has an authorized, issued and outstanding capitalization as set forth in the Registration Statement and the Prospectus as of the dates referred to therein (other than the grant of additional options or other equity awards pursuant to the Company's existing equity incentive plans, or changes in the number of outstanding shares of Common Stock of the Company due to the issuance of shares upon the exercise or conversion of securities exercisable for, or convertible into, Common Stock outstanding on the date hereof, or the vesting of restricted stock units outstanding on the date hereof) and such authorized capital stock conforms in all material respects to the description thereof set forth in the Registration Statement and the Prospectus. The description of the common stock of the Company in the Registration Statement and the Prospectus is complete and accurate in all material respects. Except as disclosed in or contemplated by the Registration Statement or the Prospectus, as of the date referred to therein, the Company does not have outstanding any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or exchangeable for, or any contracts or commitments to issue or sell, any shares of capital stock or other securities.

(k) Authorization; Enforceability. The Company has full legal right, power and authority to enter into this Agreement and perform the transactions contemplated hereby. This Agreement has been duly authorized, executed and delivered by the Company and is a legal, valid and binding agreement of the Company enforceable in accordance with its terms, except to the extent that enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles.

(l) Authorization of Placement Shares. The Placement Shares, when issued and delivered pursuant to the terms approved by the board of directors of the Company or a duly authorized committee thereof, or a duly authorized executive or executive committee, against payment therefor as provided herein, will be duly and validly authorized and issued and fully paid and nonassessable, free and clear of any pledge, lien, encumbrance, security interest or other claim (other than any pledge, lien, encumbrance, security interest or other claim arising from an act or omission of the Agent or a purchaser), including any statutory or contractual preemptive



rights, resale rights, rights of first refusal or other similar rights, and will be registered pursuant to Section 12 of the Exchange Act. The Placement Shares, when issued, will conform in all material respects to the description thereof set forth in or incorporated into the Prospectus.

(m) No Consents Required. No consent, approval, authorization, order, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement or the issuance and sale by the Company of the Placement Shares, except for such consents, approvals, authorizations, orders and registrations or qualifications as may be required under applicable state securities laws or by the by-laws and rules of the Financial Industry Regulatory Authority ("FINRA") or the Exchange in connection with the sale of the Placement Shares by the Agent.

(n) No Preferential Rights. Except as set forth in the Registration Statement and the Prospectus, (i) no person, as such term is defined in Rule 1-02 of Regulation S-X promulgated under the Securities Act (each, a "Person"), has the right, contractual or otherwise, to cause the Company to issue or sell to such Person any Common Stock or shares of any other capital stock or other securities of the Company (other than outstanding options or warrants to purchase Common Stock or options or other equity securities that may be granted from time to time under the Company's equity incentive plans which are disclosed in the Registration Statement and Prospectus), (ii) no Person has any preemptive rights, resale rights, rights of first refusal, rights of co-sale or any other rights (whether pursuant to a "poison pill" provision or otherwise) to purchase any Common Stock or shares of any other capital stock or other securities of the Company, (iii) no Person has the right to act as an underwriter or as a financial advisor to the Company in connection with the offer and sale of the Common Stock, and (iv) no Person has the right, contractual or otherwise, to require the Company to register under the Securities Act any Common Stock or shares of any other capital stock or other securities of the Company, or to include any such shares or other securities in the Registration Statement or the offering contemplated thereby, whether as a result of the filing or effectiveness of the Registration Statement or the sale of the Placement Shares as contemplated thereby or otherwise.

(o) Independent Public Accounting Firm. Ernst & Young LLP (the "Accountant"), whose report on the consolidated financial statements of the Company is filed with the Commission as part of the Company's most recent Annual Report on Form 10-K filed with the Commission and incorporated by reference into the Registration Statement and the Prospectus, are and, during the periods covered by their report, were an independent registered public accounting firm within the meaning of the Securities Act and the Public Company Accounting Oversight Board (United States). To the Company's knowledge, the Accountant is not in violation of the auditor independence requirements of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act") with respect to the Company.

(p) Enforceability of Agreements. All agreements between the Company and third parties expressly referenced in the Prospectus, other than such agreements that have expired by their terms or whose termination is disclosed in the Registration Statement and the Prospectus, are legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, except to the extent that (i) enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and by general equitable principles and (ii) the indemnification provisions of certain

agreements may be limited by federal or state securities laws or public policy considerations in respect thereof, except for any unenforceability that, individually or in the aggregate, would not have a Material Adverse Effect.

(q) No Litigation. Except as set forth in the Registration Statement or the Prospectus, there are no legal, governmental or regulatory actions, suits or proceedings pending, nor, to the Company's knowledge, any legal, governmental or regulatory audits or investigations, to which the Company or its Subsidiaries are a party or to which any property of the Company or its Subsidiaries are the subject that, individually or in the aggregate, if determined adversely to the Company or its Subsidiaries, would reasonably be expected to have a Material Adverse Effect; to the Company's knowledge, no such actions, suits or proceedings are threatened or contemplated by any governmental or regulatory authority or threatened by others; and (i) there are no current or pending legal, governmental or regulatory audits or investigations, actions, suits or proceedings that are required under the Securities Act to be described in the Prospectus that are not so described; and (ii) there are no contracts or other documents that are required under the Securities Act to be filed as exhibits to the Registration Statement that are not so filed.

(r) Consents and Permits. Except as disclosed in the Registration Statement and the Prospectus, the Company and its Subsidiaries have made all filings, applications and submissions required by, possesses and is operating in compliance with, all approvals, licenses, certificates, certifications, clearances, consents, grants, exemptions, marks, notifications, orders, permits, registrations, and other authorizations issued by, the appropriate federal, state or foreign governmental or regulatory authorities (including, without limitation, the United States Food and Drug Administration (the "**FDA**"), the United States Drug Enforcement Administration or any other foreign, federal, state, provincial, court or local government or regulatory authorities including self-regulatory organizations engaged in the regulation of clinical trials, pharmaceuticals, biologics or biohazardous substances or materials) necessary for the ownership or lease of their respective properties or to conduct its businesses as described in the Registration Statement and the Prospectus (collectively, "**Permits**"), except for such Permits the failure of which to possess, obtain or make the same would not reasonably be expected to have a Material Adverse Effect; the Company and its Subsidiaries are in compliance with the terms and conditions of all such Permits, except where the failure to be in compliance would not reasonably be expected to have a Material Adverse Effect; all of the Permits are valid and in full force and effect, except where any invalidity, individually or in the aggregate, would not be reasonably expected to have a Material Adverse Effect; and neither the Company nor its Subsidiaries have received any written notice of proceedings relating to the limitation, revocation, cancellation, suspension, modification or non-renewal of any such Permit which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would reasonably be expected to have a Material Adverse Effect, or has any reason to believe that any such license, certificate, permit or authorization will not be renewed in the ordinary course. To the extent required by applicable laws and regulations of the FDA, the Company or the applicable Subsidiaries have submitted to the FDA an Investigational New Drug Application or amendment or supplement thereto for each clinical trial it has conducted or sponsored or is conducting or sponsoring in the United States; all such submissions were in material compliance with applicable laws and rules and regulations when submitted and no material deficiencies have been asserted by the FDA with respect to any such submissions.

(s) **Regulatory Filings.** Except as disclosed in the Registration Statement and the Prospectus, neither the Company nor its Subsidiaries have failed to file with the applicable regulatory authorities (including, without limitation, the FDA, or any foreign, federal, state, provincial or local governmental or regulatory authority performing functions similar to those performed by the FDA) any required filing, declaration, listing, registration, report or submission, except for such failures that, individually or in the aggregate, would not reasonably be expected to have a Material Adverse Effect; except as disclosed in the Registration Statement and the Prospectus, all such filings, declarations, listings, registrations, reports or submissions were in compliance in all material respects with applicable laws when filed and no deficiencies have been asserted by any applicable regulatory authority with respect to any such filings, declarations, listings, registrations, reports or submissions, except for any deficiencies that, individually or in the aggregate, would not have a Material Adverse Effect. The Company has operated and currently is, in all material respects, in compliance with the United States Federal Food, Drug, and Cosmetic Act, all applicable rules and regulations of the FDA and other federal, state, local and foreign governmental bodies exercising comparable authority.

(t) **Intellectual Property.** Except as disclosed in the Registration Statement and the Prospectus, the Company and its Subsidiaries own, possess, license or have other rights to use all foreign and domestic patents, patent applications, trade and service marks, trade and service mark registrations, trade names, copyrights, licenses, inventions, trade secrets, technology, Internet domain names, know-how and other intellectual property (collectively, the “**Intellectual Property**”), necessary for the conduct of their respective businesses as now conducted except to the extent that the failure to own, possess, license or otherwise hold adequate rights to use such Intellectual Property would not, individually or in the aggregate, have a Material Adverse Effect. Except as disclosed in the Registration Statement and the Prospectus (i) to the Company’s knowledge, there are no rights of third parties to any such Intellectual Property owned by the Company and its Subsidiaries other than any co-owner of any patent or patent application constituting Intellectual Property who is listed as such on the records of the U.S. Patent and Trademark Office; (ii) to the Company’s knowledge, there is no infringement by third parties of any such Intellectual Property; (iii) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the Company’s and its Subsidiaries’ rights in or to any such Intellectual Property, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim; (iv) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property; (v) there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others that the Company and its Subsidiaries infringe or otherwise violate any patent, trademark, copyright, trade secret or other proprietary rights of others; (vi) to the Company’s knowledge, there is no third-party U.S. patent or published U.S. patent application which contains claims for which an Interference Proceeding (as defined in 35 U.S.C. § 135) has been commenced against any patent or patent application described in the Prospectus as being owned by or licensed to the Company; and (vii) the Company and its Subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or its Subsidiaries, and all such agreements are in full force and effect (except for agreements that have been terminated), except, in the case of any of clauses (i)-(vii) above, for any such infringement by third parties or any such pending or threatened suit, action, proceeding or claim as would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(u) Clinical Studies. The preclinical studies and tests and clinical trials described in the Registration Statement and the Prospectus being conducted by or on behalf of the Company were, and, if still pending, are being conducted in all material respects in accordance with the experimental protocols, procedures and controls pursuant to, where applicable, accepted medical and scientific standards for products or product candidates comparable to those being developed by the Company and all applicable laws; the descriptions of such studies, tests and trials, and the results thereof, contained in the Prospectus are accurate and complete in all material respects; the Company is not aware of any tests, studies or trials not described in the Prospectus, the results of which reasonably call into question the results of the tests, studies and trials described in the Prospectus; and the Company has not received any written notice or correspondence from the FDA or any foreign, state or local governmental body exercising comparable authority (performing functions similar to those performed by the FDA) or any institutional review board or comparable authority requiring the termination, suspension, clinical hold or material modification of any tests, studies or trials that are described or referred to in the Registration Statement and the Prospectus.

(v) Market Capitalization. At the time the Registration Statement was originally declared effective, and at the time the Company's most recent Annual Report on Form 10-K was filed with the Commission, the Company met or will meet the then applicable requirements for the use of Form S-3 under the Securities Act, including but not limited to Instruction I.B.1 of Form S-3. The aggregate market value of the outstanding voting and non-voting common equity (as defined in Securities Act Rule 405) of the Company held by persons other than affiliates of the Company (pursuant to Securities Act Rule 144, those that directly, or indirectly through one or more intermediaries, control, or are controlled by, or are under common control with, the Company) (the "Non-Affiliate Shares"), was greater than \$75 million (calculated by multiplying (x) the highest price at which the common equity of the Company closed on the Exchange within 60 days of the date of the filing of the Registration Statement times (y) the number of Non-Affiliate Shares). The Company is not a shell company (as defined in Rule 405 under the Securities Act) and has not been a shell company for at least 12 calendar months previously and if it has been a shell company at any time previously, has filed current Form 10 information (as defined in Instruction I.B.6 of Form S-3) with the Commission at least 12 calendar months previously reflecting its status as an entity that is not a shell company.

(w) No Material Defaults. Neither the Company nor its Subsidiaries have defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect. The Company has not filed a report pursuant to Section 13(a) or 15(d) of the Exchange Act since the filing of its last Annual Report on Form 10-K, indicating that it (i) has failed to pay any dividend or sinking fund installment on preferred stock or (ii) has defaulted on any installment on indebtedness for borrowed money or on any rental on one or more long-term leases, which defaults, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect.

(x) Certain Market Activities. Neither the Company, nor its Subsidiaries, nor any of their respective directors, officers or controlling persons have taken, directly or indirectly, any action designed, or that has constituted or would reasonably be expected to cause or result in, under the Exchange Act or otherwise, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares.

(y) Broker/Dealer Relationships. Neither the Company nor its Subsidiaries (i) are required to register as a “broker” or “dealer” in accordance with the provisions of the Exchange Act or (ii) directly or indirectly through one or more intermediaries, control or are a “person associated with a member” or “associated person of a member” (within the meaning set forth in the FINRA Manual).

(z) No Reliance. The Company has not relied upon the Agent or legal counsel for the Agent for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(aa) Taxes. The Company and its Subsidiaries have filed all federal, state, local and foreign tax returns which have been required to be filed and paid all taxes shown thereon through the date hereof, to the extent that such taxes have become due and are not being contested in good faith, except where the failure to so file or pay would not have a Material Adverse Effect. Except as otherwise disclosed in or contemplated by the Registration Statement or the Prospectus, no tax deficiency has been determined adversely to the Company or its Subsidiaries that has had, or would reasonably be expected to have, individually or in the aggregate, a Material Adverse Effect. The Company has no knowledge of any federal, state or other governmental tax deficiency, penalty or assessment that has been or might be asserted or threatened against it which would have a Material Adverse Effect.

(bb) Title to Real and Personal Property. Except as set forth in the Registration Statement or the Prospectus, the Company and its Subsidiaries have good and marketable title in fee simple to all items of real property owned by them, good and valid title to all personal property described in the Registration Statement or Prospectus as being owned by them that are material to the businesses of the Company or its Subsidiaries, in each case free and clear of all liens, encumbrances and claims, except those matters that (i) do not materially interfere with the use made and proposed to be made of such property by the Company and its Subsidiaries or (ii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. Any real or personal property described in the Registration Statement or Prospectus as being leased by the Company and its Subsidiaries is held by them under valid, existing and enforceable leases, except those that (A) do not materially interfere with the use made or proposed to be made of such property by the Company or its Subsidiaries or (B) would not be reasonably expected, individually or in the aggregate, to have a Material Adverse Effect. Each of the properties of the Company and its Subsidiaries complies with all applicable codes, laws and regulations (including, without limitation, building and zoning codes, laws and regulations and laws relating to access to such properties), except to the extent disclosed in the Registration Statement or Prospectus or except for such failures to comply that would not, individually or in the aggregate, reasonably be expected to interfere in any material respect with the use made and proposed to be made of such property by the Company and its Subsidiaries or otherwise have a Material Adverse Effect. None of the Company or its Subsidiaries has received from any governmental or regulatory authorities any notice of any condemnation of, or zoning change affecting, the properties of the Company and its Subsidiaries, and the Company knows of no such condemnation or zoning change which is threatened, except for such that would not reasonably be expected to interfere in any material respect with the use made and proposed to be made of such property by the Company and its Subsidiaries or otherwise have a Material Adverse Effect, individually or in the aggregate.

(cc) **Environmental Laws.** Except as set forth in the Registration Statement or the Prospectus, the Company and its Subsidiaries (i) are in compliance with any and all applicable federal, state, local and foreign laws, rules, regulations, decisions and orders relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "**Environmental Laws**"); (ii) have received and are in compliance with all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses as described in the Registration Statement and the Prospectus; and (iii) have not received notice of any actual or potential liability for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, except, in the case of any of clauses (i), (ii) or (iii) above, for any such failure to comply or failure to receive required permits, licenses, other approvals or liability as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(dd) **Disclosure Controls.** The Company maintains a consolidated 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. As of the end of the Company's most recently completed fiscal year, the Company's internal control over financial reporting was effective and as of the end of the most recently completed fiscal year, the Company is not aware of any material weaknesses in its internal control over financial reporting (other than as set forth in the Prospectus). Since the date of the latest audited financial statements of the Company included in the Prospectus, there has been 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 (other than as set forth in the Prospectus). The Company has established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15 and 15d-15) for the Company and designed such disclosure controls and procedures to ensure that material information relating to the Company and its Subsidiaries is made known to the certifying officers by others within those entities, particularly during the period in which the Company's Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as the case may be, is being prepared. The Company's certifying officers have evaluated the effectiveness of the Company's controls and procedures as of a date within 90 days prior to the filing date of the Form 10-K for the fiscal year most recently ended (such date, the "**Evaluation Date**"). The Company presented in its Form 10-K for the fiscal year most recently ended the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date and the disclosure controls and procedures were effective. Since the Evaluation Date, there have been no significant changes in the Company's internal controls (as such term is defined in Item 307(b) of Regulation S-K under the Securities Act) or, to the Company's knowledge, in other factors that could significantly affect the Company's internal controls.

(ee) Sarbanes-Oxley. There is and has been no failure on the part of the Company or, to the Company's knowledge, any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any applicable provisions of the Sarbanes-Oxley Act and the rules and regulations promulgated thereunder. Each of the principal executive officer and the principal financial officer of the Company (or each former principal executive officer of the Company and each former principal financial officer of the Company as applicable) has made all certifications required by Sections 302 and 906 of the Sarbanes-Oxley Act with respect to all reports, schedules, forms, statements and other documents required to be filed by it or furnished by it to the Commission. For purposes of the preceding sentence, "principal executive officer" and "principal financial officer" shall have the meanings given to such terms in the Sarbanes-Oxley Act.

(ff) Finder's Fees. Neither the Company nor its Subsidiaries have incurred any liability for any finder's fees, brokerage commissions or similar payments in connection with the transactions herein contemplated, except as may otherwise exist with respect to Agent pursuant to this Agreement.

(gg) Labor Disputes. No labor disturbance by or dispute with employees of the Company or its Subsidiaries exist or, to the knowledge of the Company, are threatened which would reasonably be expected to result in a Material Adverse Effect.

(hh) Investment Company Act. Neither the Company nor its Subsidiaries are or, after giving effect to the offering and sale of the Placement Shares, will be an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended (the "**Investment Company Act**").

(ii) Operations. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions to which the Company or its Subsidiaries are subject, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**"), except as would not reasonably be expected to result in a Material Adverse Effect; and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its Subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(jj) Off-Balance Sheet Arrangements. There are no transactions, arrangements and other relationships between and/or among the Company, and/or, to the knowledge of the Company, any of its affiliates and any unconsolidated entity, including, but not limited to, any structural finance, special purpose or limited purpose entity (each, an "**Off Balance Sheet Transaction**") that could reasonably be expected to affect materially the Company's liquidity or the availability of or requirements for its capital resources, including those Off Balance Sheet Transactions described in the Commission's Statement about Management's Discussion and Analysis of Financial Conditions and Results of Operations (Release Nos. 33-8056; 34-45321; FR-61), required to be described in the Prospectus which have not been described as required.

(kk) Underwriter Agreements. The Company is not a party to any agreement with an agent or underwriter for any other “at-the-market” or continuous equity transaction.

(ll) ERISA. To the knowledge of the Company, each material employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended (“**ERISA**”), that is maintained, administered or contributed to by the Company or its Subsidiaries for employees or former employees of the Company and its Subsidiaries have been maintained in material compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Internal Revenue Code of 1986, as amended (the “**Code**”); no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred which would result in a material liability to the Company with respect to any such plan excluding transactions effected pursuant to a statutory or administrative exemption; and for each such plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no “accumulated funding deficiency” as defined in Section 412 of the Code has been incurred, whether or not waived, and the fair market value of the assets of each such plan (excluding for these purposes accrued but unpaid contributions) exceeds the present value of all benefits accrued under such plan determined using reasonable actuarial assumptions.

(mm) Forward Looking Statements. No forward-looking statement (within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act) (a “**Forward Looking Statement**”) contained in the Registration Statement and the Prospectus has been made or reaffirmed without a reasonable basis or has been disclosed other than in good faith.

(nn) Agent Purchases. The Company acknowledges and agrees that the Agent has informed the Company that the Agent may, to the extent permitted under the Securities Act and the Exchange Act, purchase and sell Common Stock for its own account while this Agreement is in effect, provided, that (i) no such purchase or sales shall take place while a Placement Notice is in effect (except to the extent each Agent may engage in sales of Placement Shares purchased or deemed purchased from the Company as a “riskless principal” or in a similar capacity) and (ii) the Company shall not be deemed to have authorized or consented to any such purchases or sales by the Agent.

(oo) Margin Rules. Neither the issuance, sale and delivery of the Placement Shares nor the application of the proceeds thereof by the Company as described in the Registration Statement and the Prospectus will violate Regulation T, U or X of the Board of Governors of the Federal Reserve System or any other regulation of such Board of Governors.

(pp) Insurance. The Company and its Subsidiaries carry, or are covered by, insurance in such amounts and covering such risks as the Company and its Subsidiaries reasonably believe are adequate for the conduct of their properties and as is customary for companies engaged in similar businesses in similar industries.

(qq) No Improper Practices. (i) Neither the Company nor, to the Company’s knowledge, the Subsidiaries, nor to the Company’s knowledge, any of their respective executive officers have, in the past five years, made any unlawful contributions to any candidate for any political office (or failed fully to disclose any contribution in violation of law) or made any



contribution or other payment to any official of, or candidate for, any federal, state, municipal, or foreign office or other person charged with similar public or quasi-public duty in violation of any law or of the character required to be disclosed in the Prospectus; (ii) no relationship, direct or indirect, exists between or among the Company or, to the Company's knowledge, the Subsidiaries, on the one hand, and the directors, officers and stockholders of the Company or, to the Company's knowledge, of the Subsidiaries, on the other hand, that is required by the Securities Act to be described in the Registration Statement and the Prospectus that is not so described; (iii) except as described in the Prospectus, there are no material outstanding loans or advances or material guarantees of indebtedness by the Company or, to the Company's knowledge, the Subsidiaries to or for the benefit of any of their respective officers or directors or any of the members of the families of any of them; (iv) the Company has not offered, or caused any placement agent to offer, Common Stock to any person with the intent to influence unlawfully (A) a customer or supplier of the Company or the Subsidiaries to alter the customer's or supplier's level or type of business with the Company or the Subsidiaries or (B) a trade journalist or publication to write or publish favorable information about the Company or the Subsidiaries or any of their respective products or services, and, (v) neither the Company nor the Subsidiaries nor, to the Company's knowledge, any employee or agent of the Company or the Subsidiaries have made any payment of funds of the Company or the Subsidiaries or received or retained any funds in violation of any law, rule or regulation (including, without limitation, the Foreign Corrupt Practices Act of 1977), which payment, receipt or retention of funds is of a character required to be disclosed in the Registration Statement or the Prospectus.

(rr) Status Under the Securities Act. The Company was not and is not an ineligible issuer as defined in Rule 405 under the Securities Act at the times specified in Rules 164 and 433 under the Securities Act in connection with the offering of the Placement Shares.

(ss) No Misstatement or Omission in an Issuer Free Writing Prospectus. Each Issuer Free Writing Prospectus, as of its issue date and as of each Applicable Time (as defined in Section 25 below), did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, including any Incorporated Document that has not been superseded or modified. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with written information furnished to the Company by the Agent specifically for use therein.

(tt) No Conflicts. Neither the execution of this Agreement, nor the issuance, offering or sale of the Placement Shares, nor the consummation of any of the transactions contemplated herein and therein, nor the compliance by the Company with the terms and provisions hereof and thereof will conflict with, or will result in a breach of, any of the terms and provisions of, or has constituted or will constitute a default under, or has resulted in or will result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any contract or other agreement to which the Company may be bound or to which any of the property or assets of the Company is subject, except (i) such conflicts, breaches or defaults as may have been waived and (ii) such conflicts, breaches and defaults that would not have a Material Adverse Effect; nor will such action result (x) in any violation of the provisions of the organizational or governing documents of the Company, or (y) in any material violation of the provisions of any statute or any order, rule or regulation applicable to the Company or of any court or of any federal, state or other regulatory authority or other government body having jurisdiction over the Company.

(uu) Sanctions. (i) The Company represents that, neither the Company nor any of its Subsidiaries (collectively, the “**Entity**”) or, to the Company’s knowledge, any director, officer or employee of the Entity, a government, individual, or entity (in this paragraph (uu), “**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, the United Nations Security Council, the European Union, Her Majesty’s Treasury, 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, Burma/Myanmar, Crimea, Iran, North Korea, Sudan and Syria).

(ii) The Entity represents and covenants that it 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) The Entity represents and covenants that, except as detailed in the Registration Statement and the Prospectus, for the past 5 years, it has not knowingly engaged in, is not now knowingly engaged in, and will not knowingly engage 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.

(vv) Stock Transfer Taxes. On each Settlement Date, all stock transfer or other taxes (other than income taxes) which are required to be paid in connection with the sale and transfer of the Placement Shares to be sold hereunder will be, or will have been, fully paid or provided for by the Company and all laws imposing such taxes will be or will have been fully complied with.

(ww) Compliance with Laws. The Company and its Subsidiaries, and to the Company’s knowledge, their respective directors, officers, employees, agents, affiliates and representatives, are, and at all times have been, in compliance in all material respects with all healthcare laws and regulations applicable to the Company or its subsidiaries or any of their respective products or activities, including all Applicable Laws as defined below. Each of the Company and its Subsidiaries: (A) have not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the FDA or any

other governmental authority alleging or asserting noncompliance with any Applicable Laws or any Permits; (B) have not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Permits and has no knowledge that any such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding. "Applicable Laws" means all statutes, rules, or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company or its Subsidiaries, and includes, without limitation, 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, and has 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 and its subsidiaries have 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 or its subsidiaries under any Applicable Laws. Additionally, neither the Company nor any of its Subsidiaries nor, to the Company's knowledge, any of their respective employees, officers, directors, agents or contractors has been excluded, suspended or debarred from participation in any federal health care program or, to the knowledge of Company and its Subsidiaries, is subject to an inquiry, investigation, proceeding, or other similar matter that could subject the Company, any of its Subsidiaries, or any of their respective employees, officers, directors, agents or contractors to exclusion, suspension or debarment. The Company and its subsidiaries are not a party to or have 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.

Any certificate signed by an officer of the Company and delivered to the Agent or to counsel for the Agent pursuant to or in connection with this Agreement shall be deemed to be a representation and warranty by the Company, as applicable, to the Agent as to the matters set forth therein.

7. Covenants of the Company. The Company covenants and agrees with Agent that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by Agent under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify the

Agent promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information, (ii) the Company will prepare and file with the Commission, promptly upon the Agent's request, any amendments or supplements to the Registration Statement or Prospectus that, in such Agent's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by the Agent (provided, however, that the failure of the Agent to make such request shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and provided, further, that the only remedy the Agent shall have with respect to the failure to make such filing shall be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to Agent within a reasonable period of time before the filing and the Agent has not objected thereto in good faith with reasonable grounds (provided, however, that the failure of the Agent to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect the Agent's right to rely on the representations and warranties made by the Company in this Agreement and provided, further, that the only remedy Agent shall have with respect to the failure by the Company to obtain such consent shall be to cease making sales under this Agreement, and provided, for the avoidance of doubt, that this provision shall not apply to documents the Company furnishes to the SEC under the Exchange Act) and the Company will furnish to the Agent at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; and (iv) the Company will cause each amendment or supplement to the Prospectus relating to the Placement Shares to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act or, in the case of any document to be incorporated therein by reference, to be filed with the Commission as required pursuant to the Exchange Act, within the time period prescribed (the determination to file or not file any amendment or supplement with the Commission under this Section 7(a), based on the Company's reasonable opinion or reasonable objections, shall be made exclusively by the Company).

(b) Notice of Commission Stop Orders. The Company will advise the Agent, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued. The Company will advise the Agent promptly after it receives any request by the Commission for any amendments to the Registration Statement or any amendment or supplements to the Prospectus or any Issuer Free Writing Prospectus or for additional information related to the offering of the Placement Shares or for additional information related to the Registration Statement, the Prospectus or any Issuer Free Writing Prospectus.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by the Agent under the Securities Act with respect to the offer and sale of the Placement Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If the Company has omitted any information from the Registration Statement pursuant to Rule 430B under the Securities Act, it will use its best efforts to comply with the provisions of and make all requisite filings with the Commission pursuant to said Rule 430B and to notify the Agent promptly of all such filings relating to the Placement Shares. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an 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 then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify Agent to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; provided, however, that the Company may delay such amendment or supplement if, in the reasonable judgment of the Company, it is in the best interests of the Company to do so. Until such time as the Company shall have corrected such misstatement or omission or effected such compliance, the Company shall not notify the Agent to resume the offering of Placement Shares.

(d) Listing of Placement Shares. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by the Agent under the Securities Act with respect to the offer and sale of the Placement Shares, the Company will use its reasonable best efforts to cause the Placement Shares to be listed on the Exchange.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to the Agent and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all Incorporated Documents) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all Incorporated Documents filed with the Commission during such period), in each case as soon as reasonably practicable and in such quantities as the Agent may from time to time reasonably request and, at the Agent's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; provided, however, that the Company shall not be required to furnish any document (other than the Prospectus) to the Agent to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled “Use of Proceeds.”

(h) Notice of Other Sales. Without the prior written consent of Agent, the Company will not, directly or indirectly, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock during the period beginning on the fifth (5th) Trading Day immediately prior to the date on which any Placement Notice is delivered to Agent hereunder and ending on the third (3rd) Trading Day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice (or, if the Placement Notice has been terminated or suspended prior to the sale of all Placement Shares covered by a Placement Notice, the date of such suspension or termination); and will not directly or indirectly in any other “at-the-market” offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of any Common Stock (other than the Placement Shares offered pursuant to this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire, Common Stock prior to the later of the termination of this Agreement and the thirtieth (30th) day immediately following the final Settlement Date with respect to Placement Shares sold pursuant to such Placement Notice; provided, however, that such restrictions will not be required in connection with the Company’s issuance or sale of (i) Common Stock, options to purchase Common Stock or Common Stock issuable upon the exercise of options, pursuant to any employee or director equity incentive or benefits plan, stock ownership plan or dividend reinvestment plan (but not Common Stock subject to a waiver to exceed plan limits in its dividend reinvestment plan) of the Company whether now in effect or hereafter implemented, (ii) Common Stock issuable upon conversion of securities or the exercise of warrants, options or other rights in effect or outstanding, and disclosed in filings by the Company available on EDGAR or otherwise in writing to the Agent and (iii) Common Stock or securities convertible into or exchangeable for shares of Common Stock as consideration for mergers, acquisitions, licensing, other business combinations, or strategic alliances or corporate partnering transactions occurring after the date of this Agreement which are not issued for capital raising purposes.

(i) Change of Circumstances. The Company will, at any time during the pendency of a Placement Notice, advise the Agent promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document required to be provided to the Agent pursuant to this Agreement.

(j) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by the Agent or its representatives in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company’s principal offices, as the Agent may reasonably request.

(k) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require the filing of a prospectus supplement with respect to the sale of Placement Shares hereunder, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act (each and every filing date under Rule 424(b), a “**Filing Date**”), which prospectus supplement will set forth, within the relevant period, the amount of Placement Shares

sold through the Agent, the Net Proceeds to the Company and the compensation payable by the Company to the Agent with respect to such Placement Shares, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market.

(l) Representation Dates; Certificate. (1) Prior to the date of the first Placement Notice and (2) each time the Company:

(i) files the Prospectus relating to the Placement Shares or amends or supplements (other than a prospectus supplement relating solely to an offering of securities other than the Placement Shares) the Registration Statement or the Prospectus relating to the Placement Shares by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of documents by reference into the Registration Statement or the Prospectus relating to the Placement Shares;

(ii) files an annual report on Form 10-K under the Exchange Act (including any Form 10-K/A containing amended financial information or a material amendment to the previously filed Form 10-K);

(iii) files its quarterly reports on Form 10-Q under the Exchange Act, excluding any quarter where no Placement has occurred unless or until the Company issues a Placement Notice in such quarter; or

(iv) files a current report on Form 8-K containing amended financial statements relating to the Company (other than information “furnished” pursuant to Items 2.02 or 7.01 of Form 8-K or to provide disclosure pursuant to Item 8.01 of Form 8-K relating to the reclassification of certain properties as discontinued operations in accordance with Statement of Financial Accounting Standards No. 144) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a “**Representation Date**”);

the Company shall furnish the Agent (but in the case of clause (iv) above only if the Agent reasonably determines that the information contained in such Form 8-K is material) with a certificate dated the Representation Date, in the form attached hereto as Exhibit 7(l). The requirement to provide a certificate under this Section 7(l) shall be waived for any Representation Date occurring at a time at which no Placement Notice is pending (including, for clarity, a time a Suspension is in effect), which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder or instructions for the sale of Placement Shares under a suspended Placement Notice (which for such calendar quarter shall be considered a Representation Date) and the next occurring Representation Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Representation Date when the Company relied on such a waiver and did not provide the Agent with a certificate under this Section 7(l), then before the Company delivers the instructions for the sale of Placement Shares or the Agent sells any Placement Shares pursuant to such instructions, the Company shall provide the Agent with a certificate in conformity with this Section 7(l) dated as of the date that the Placement Notice or the date that instructions for the sale of Placement Shares are issued.

(m) Legal Opinions. (1) Prior to the date of the first Placement Notice and (2) within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(l) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause to be furnished to the Agent a written opinion of each of (A) Ropes & Gray LLP (“**Company Counsel**”), or other counsel satisfactory to the Agent, (B) Jones Day LLP (“**IP Counsel**”), or other counsel satisfactory to the Agent, in each case in form and substance satisfactory to Agent and its counsel, substantially similar to the forms previously provided to the Agent and its counsel, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; provided, however, the Company shall be required to furnish to Agent no more than one opinion from each of Company Counsel and the IP Counsel hereunder per calendar quarter; provided, further, that in lieu of such opinions for subsequent periodic filings under the Exchange Act, counsel may furnish the Agent with a letter (a “**Reliance Letter**”) to the effect that the Agent may rely on a prior opinion delivered under this Section 7(m) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented as of the date of the Reliance Letter).

(n) Comfort Letter. (1) Prior to the date of the first Placement Notice and (2) within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(l) for which no waiver is applicable and excluding the date of this Agreement, the Company shall cause its independent registered public accounting firm to furnish the Agent letters (the “**Comfort Letters**”), dated the date the Comfort Letter is delivered, which shall meet the requirements set forth in this Section 7(n); provided, that if reasonably requested by the Agent, the Company shall cause a Comfort Letter to be furnished to the Agent within ten (10) Trading Days of the date of occurrence of any material transaction or event, including the restatement of the Company’s financial statements. The Comfort Letter from the Company’s independent registered public accounting firm shall be in a form and substance satisfactory to the Agent, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the PCAOB, (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants’ “comfort letters” to underwriters in connection with registered public offerings (the first such letter, the “**Initial Comfort Letter**”) and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(o) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or would reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of Common Stock or (ii) sell, bid for, or purchase the Placement Shares, or pay anyone any compensation for soliciting purchases of the Placement Shares other than the Agent.

(p) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor any of its Subsidiaries will be or become, at any time prior to the termination of this Agreement, required to register as an “investment company,” as such term is defined in the Investment Company Act.



(q) No Offer to Sell. Other than an Issuer Free Writing Prospectus approved in advance by the Company and the Agent in its capacity as agent hereunder, neither the Agent nor the Company (including its agents and representatives, other than the Agent in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Placement Shares hereunder.

(r) Blue Sky and Other Qualifications. The Company will use its commercially reasonable efforts, in cooperation with the Agent, to qualify the Placement Shares for offering and sale, or to obtain an exemption for the Placement Shares to be offered and sold, under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Agent may designate and to maintain such qualifications and exemptions in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement); *provided, however*, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject. In each jurisdiction in which the Placement Shares have been so qualified or exempt, the Company will file such statements and reports as may be required by the laws of such jurisdiction to continue such qualification or exemption, as the case may be, in effect for so long as required for the distribution of the Placement Shares (but in no event for less than one year from the date of this Agreement).

(s) Sarbanes-Oxley Act. The Company will maintain and keep accurate books and records reflecting its consolidated assets and maintain internal accounting controls in a manner designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and including those policies and procedures that (i) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company, (ii) provide reasonable assurance that transactions are recorded as necessary to permit the preparation of the Company's consolidated financial statements in accordance with generally accepted accounting principles, (iii) that receipts and expenditures of the Company are being made only in accordance with management's and the Company's directors' authorization, and (iv) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on its financial statements. The Company and its Subsidiaries will maintain such controls and other procedures, including, without limitation, those required by Sections 302 and 906 of the Sarbanes-Oxley Act, and the applicable regulations thereunder that are designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer and

principal financial officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure and to ensure that material information relating to the Company or its Subsidiaries is made known to them by others within those entities, particularly during the period in which such periodic reports are being prepared.

(t) Secretary's Certificate; Further Documentation. Prior to the date of the first Placement Notice, the Company shall deliver to the Agent a certificate of the Secretary of the Company and attested to by an executive officer of the Company, dated as of such date, certifying as to (i) the Certificate of Incorporation of the Company, (ii) the By-laws of the Company, (iii) the resolutions of the Board of Directors of the Company, or a duly authorized committee of the Board of Directors, authorizing the execution, delivery and performance of this Agreement and the issuance of the Placement Shares and (iv) the incumbency of the officers duly authorized to execute this Agreement and the other documents contemplated by this Agreement. Within five (5) Trading Days of each Representation Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(1), for which no waiver is applicable and excluding the date of this Agreement, the Company shall have furnished to the Agent such further information, certificates and documents as the Agent may reasonably request.

8. Payment of Expenses. The Company will pay all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation and filing of the Registration Statement, including any fees required by the Commission, and the printing or electronic delivery of the Prospectus as originally filed and of each amendment and supplement thereto relating to the Placement Shares, in such number as the Agent shall deem necessary, (ii) the printing and delivery to the Agent of this Agreement and such other documents as may be required in connection with the offering, purchase, sale, issuance or delivery of the Placement Shares, (iii) the preparation, issuance and delivery of the certificates, if any, for the Placement Shares to the Agent, including any stock or other transfer taxes and any capital duties, stamp duties or other duties or taxes payable upon the sale, issuance or delivery of the Placement Shares to the Agent, (iv) the fees and disbursements of the counsel, accountants and other advisors to the Company, (v) the out-of-pocket expenses of the Agent (including, without limitation, the fees and disbursements of the counsel to the Agent), payable upon the execution of this Agreement, in an amount not to exceed \$50,000; (vi) the qualification or exemption of the Placement Shares under state securities laws in accordance with the provisions of Section 7(r) hereof, including filing fees, but excluding fees of Agent's counsel (except as may be covered under clause (v)), (vii) the printing and delivery to the Agent of copies of any Permitted Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto relating to the Placement Shares in such number as the Agent shall deem necessary, (viii) the fees and expenses of the transfer agent and registrar for the Common Stock, (ix) the filing and other fees incident to any review by FINRA of the terms of the sale of the Placement Shares including the fees of the Agent's counsel (subject to the cap, set forth in clause (v) above), and (x) the fees and expenses incurred in connection with the listing of the Placement Shares on the Exchange.

9. Representations and Covenants of Agent. Agent represents and warrants that it is duly registered as a broker dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which Agent is exempt from registration or such registration is not otherwise required.

Agent shall continue, for the term of this Agreement, to be duly registered as a broker-dealer under FINRA, the Exchange Act and the applicable statutes and regulations of each state in which the Placement Shares will be offered and sold, except such states in which Agent is exempt from registration or such registration is not otherwise required, during the term of this Agreement. Agent will comply with all applicable laws and regulations in connection with the Placement Shares, including but not limited to Regulation M.

10. Conditions to Agent's Obligations. The obligations of the Agent hereunder with respect to a Placement will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder, to the completion by the Agent of a due diligence review satisfactory to it in its reasonable judgment, and to the continuing satisfaction (or waiver by the Agent in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall have become effective and shall be available for the sale of all Placement Shares contemplated to be issued by any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by reference untrue in any material respect or that requires the making of any changes in the Registration Statement, the Prospectus or material Incorporated Documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. The Agent shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in the Agent's reasonable opinion is material, or omits to state a fact that in the Agent's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change in the authorized capital stock of the Company or any Material Adverse Effect or

any development that would reasonably be expected to cause a Material Adverse Effect, or a downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of the Agent (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Legal Opinion. The Agent shall have received the opinions of Company Counsel and the IP Counsel required to be delivered pursuant to Section 7(m) on or before the date on which such delivery of such opinion is required pursuant to Section 7(m).

(f) Comfort Letter. The Agent shall have received the Comfort Letter required to be delivered pursuant to Section 7(n) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(n).

(g) Representation Certificate. The Agent shall have received the certificate required to be delivered pursuant to Section 7(l) on or before the date on which delivery of such certificate is required pursuant to Section 7(l).

(h) No Suspension. Trading in the Common Stock shall not have been suspended on the Exchange and the Common Stock shall not have been delisted from the Exchange.

(i) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section 7(l), the Company shall have furnished to the Agent such appropriate further information, opinions, certificates, letters and other documents as the Agent may reasonably request. All such opinions, certificates, letters and other documents will be in compliance with the provisions hereof.

(j) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(k) Approval for Listing. The Placement Shares shall either have been approved for listing quotation on the Exchange, subject only to notice of issuance, or the Company shall have filed an application for listing quotation of the Placement Shares on the Exchange at, or prior to, the issuance of any Placement Notice.

(l) FINRA. FINRA shall have raised no objection to the terms of this offering and the amount of compensation allowable or payable to the Agent as described in the Prospectus.

(m) No Termination Event. There shall not have occurred any event that would permit the Agent to terminate this Agreement pursuant to Section 13(a).

11. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless the Agent, its partners, members, directors, officers, employees and agents and each person, if any, who controls the Agent within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act as follows:

(i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading, or arising out of any untrue statement or alleged untrue statement of a material fact included in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto), or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading;

(ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, joint or several, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission; provided that (subject to Section 11(d) below) any such settlement is effected with the written consent of the Company, which consent shall not unreasonably be delayed or withheld; and

(iii) against any and all expenses whatsoever, as incurred (including the fees and disbursements of counsel), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above, provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made solely in reliance upon and in conformity with written information furnished to the Company by the Agent expressly for use in the Registration Statement (or any amendment thereto), or in any related Issuer Free Writing Prospectus or the Prospectus (or any amendment or supplement thereto).

(b) Agent Indemnification. Agent agrees to indemnify and hold harmless the Company and its directors and each officer and director of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 11(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) or any Issuer Free Writing Prospectus in reliance upon and in conformity with information relating to the Agent and furnished to the Company in writing by the Agent expressly for use therein. The Company hereby acknowledges that the only information that the Agent has furnished to the Company expressly for use in the Registration

Statement, the Prospectus or any Issuer Free Writing Prospectus (or any amendment or supplement thereto) are the statements set forth in the seventh and eighth paragraphs under the caption "Plan of Distribution" in the Prospectus.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 11 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 11, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 11 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 11 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent if such consent is required by this Section 11(c). No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 11 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (1) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (2) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

(d) Settlement Without Consent if Failure to Reimburse. If an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for reasonable fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 11(a)(ii) effected without its written consent if (1) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (2) 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 (3) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(e) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 11 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or the Agent, the Company and the Agent will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, to which the Company and the Agent may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Agent on the other hand). The relative benefits received by the Company on the one hand and the Agent on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by the Agent (before deducting expenses) from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Agent, on the other hand, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Agent, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Agent agree that it would not be just and equitable if contributions pursuant to this Section 11(e) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 11(e) shall be deemed to include, for the purpose of this Section 11(e), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim to the extent consistent with Section 11(c) hereof. Notwithstanding the foregoing provisions of this Section 11(e), the Agent shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found 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. For purposes of this Section 11(e), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of the Agent, will have the same rights to contribution as that party, and each officer and director of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 11(e), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 11(e) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 11(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 11(c) hereof.

12. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 11 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of the Agent, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

13. Termination.

(a) The Agent may terminate this Agreement, by notice to the Company, as hereinafter specified at any time (1) if there has been, since the time of execution of this Agreement or since the date as of which information is given in the Prospectus, any change, or any development or event involving a prospective change, in the condition, financial or otherwise, or in the business, properties, earnings, results of operations or prospects of the Company and its Subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, which individually or in the aggregate, in the sole judgment of the Agent is material and adverse and makes it impractical or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (2) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Agent, impracticable or inadvisable to market the Placement Shares or to enforce contracts for the sale of the Placement Shares, (3) if trading in the Common Stock has been suspended or limited by the Commission or the Exchange, or if trading generally on the Exchange has been suspended or limited, or minimum prices for trading have been fixed on the Exchange, (4) if any suspension of trading of any securities of the Company on any exchange or in the over-the-counter market shall have occurred and be continuing, (5) if a major disruption of securities settlements or clearance services in the United States shall have occurred and be continuing, or



(6) if a banking moratorium has been declared by either U.S. Federal or New York authorities. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8 (Payment of Expenses), Section 11 (Indemnification and Contribution), Section 12 (Representations and Agreements to Survive Delivery), Section 18 (Governing Law and Time; Waiver of Jury Trial) and Section 19 (Consent to Jurisdiction) hereof shall remain in full force and effect notwithstanding such termination. If the Agent elects to terminate this Agreement as provided in this Section 13(a), the Agent shall provide the required notice as specified in Section 14 (Notices).

(b) The Company shall have the right, by giving ten (10) days' notice (or three (3) days' notice at any time when no Placement Notice is in effect) as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(c) The Agent shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 8, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 13, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through the Agent on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section 8, Section 11, Section 12, Section 18 and Section 19 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 13(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 8, Section 11, Section 12, Section 18 and Section 19 shall remain in full force and effect.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; provided, however, that such termination shall not be effective until the close of business on the date of receipt of such notice by the Agent or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

14. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified, and if sent to the Agent, shall be delivered to:

Cantor Fitzgerald & Co.  
499 Park Avenue  
New York, NY 10022  
Attention: Capital Markets  
Facsimile: (212) 307-3730

with copies to

Cantor Fitzgerald & Co.  
499 Park Avenue  
New York, NY 10022  
Attention: General Counsel  
Facsimile: (212) 307-3730

and with a copy to:

Latham & Watkins LLP  
12670 High Bluff Drive  
San Diego, CA 92130  
Attention: Cheston J. Larson, Esq.  
Facsimile: (858) 523-5450

and if to the Company, shall be delivered to:

Akebia Therapeutics, Inc.  
245 First Street, Suite 1100  
Cambridge, MA 02142  
Attention: Jason A. Amello and Nicole R. Hadas  
E-mail: jamello@akebia.com; nhadas@akebia.com

with a copy to:

Ropes & Gray LLP  
Prudential Tower, 800 Boylston Street  
Boston, MA 02199  
Attention: Paul Kinsella  
E-Mail: paul.kinsella@ropesgray.com

Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day or, if such day is not a Business Day, on the next succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which the Exchange and commercial banks in the City of New York are open for business.

An electronic communication ("**Electronic Notice**") shall be deemed written notice for purposes of this Section 14 if sent to the electronic mail address specified by the receiving party

under separate cover. Electronic Notice shall be deemed received at the time the party sending Electronic Notice receives verification of receipt by the receiving party. Any party receiving Electronic Notice may request and shall be entitled to receive the notice on paper, in a nonelectronic form (“**Nonelectronic Notice**”) which shall be sent to the requesting party within ten (10) days of receipt of the written request for Nonelectronic Notice.

15. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and the Agent and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 11 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. 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 assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; provided, however, that the Agent may assign its rights and obligations hereunder to an affiliate thereof without obtaining the Company’s consent so long as such affiliate is a registered broker dealer and Agent provides advance notice of such assignment to the Company.

16. Adjustments for Stock Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any stock split, stock dividend or similar event effected with respect to the Placement Shares.

17. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and the Agent. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

**18. GOVERNING LAW AND TIME; WAIVER OF JURY TRIAL. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO THE PRINCIPLES OF CONFLICTS OF LAWS. SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME. THE COMPANY HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.**

19. **CONSENT TO JURISDICTION.** EACH PARTY AGREES THAT ALL LEGAL PROCEEDINGS CONCERNING THE INTERPRETATION, ENFORCEMENT OR DEFENSE OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT OR ANY OTHER TRANSACTION DOCUMENTS (WHETHER BROUGHT AGAINST A PARTY HERETO OR ITS RESPECTIVE AFFILIATES, DIRECTORS, OFFICERS, SHAREHOLDERS, PARTNERS, MEMBERS, EMPLOYEES OR AGENTS) SHALL BE COMMENCED EXCLUSIVELY IN THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN. EACH PARTY HEREBY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF THE STATE AND FEDERAL COURTS SITTING IN THE CITY OF NEW YORK, BOROUGH OF MANHATTAN, FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH ANY TRANSACTION CONTEMPLATED HEREBY, AND HEREBY IRREVOCABLY WAIVES, AND AGREES NOT TO ASSERT IN ANY SUIT, ACTION OR PROCEEDING, ANY CLAIM THAT IT IS NOT PERSONALLY SUBJECT TO THE JURISDICTION OF ANY SUCH COURT, THAT SUCH SUIT, ACTION OR PROCEEDING IS BROUGHT IN AN INCONVENIENT FORUM OR THAT THE VENUE OF SUCH SUIT, ACTION OR PROCEEDING IS IMPROPER. EACH PARTY HEREBY IRREVOCABLY WAIVES PERSONAL SERVICE OF PROCESS AND CONSENTS TO PROCESS BEING SERVED IN ANY SUCH SUIT, ACTION OR PROCEEDING BY MAILING A COPY THEREOF (CERTIFIED OR REGISTERED MAIL, RETURN RECEIPT REQUESTED) TO SUCH PARTY AT THE ADDRESS IN EFFECT FOR NOTICES TO IT UNDER THIS AGREEMENT AND AGREES THAT SUCH SERVICE SHALL CONSTITUTE GOOD AND SUFFICIENT SERVICE OF PROCESS AND NOTICE THEREOF. NOTHING CONTAINED HEREIN SHALL BE DEEMED TO LIMIT IN ANY WAY ANY RIGHT TO SERVE PROCESS IN ANY MANNER PERMITTED BY LAW.

20. Use of Information. The Agent may not provide, disclose or otherwise make available any information gained in connection with this Agreement and the transactions contemplated by this Agreement, including due diligence, to any third party, other than its legal counsel advising it on this Agreement unless expressly approved by the Company in writing. Notwithstanding the foregoing or anything herein to the contrary, the Agent or its representatives may, if requested by any governmental, regulatory or self-regulatory agency or authority having jurisdiction over such entity, disclose information provided by the Company without notice to or consent from the Company without causing a breach of this Agreement.

21. Counterparts. 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. Delivery of an executed Agreement by one party to the other may be made by facsimile transmission.

22. Effect of Headings.

The section and exhibit headings herein are for convenience only and shall not affect the construction hereof.

23. Permitted Free Writing Prospectuses.

The Company represents, warrants and agrees that, unless it obtains the prior consent of the Agent, which shall not be unreasonably withheld, conditioned or delayed, and the Agent represents, warrants and agrees that, unless it obtains the prior consent of the Company, which shall not be unreasonably withheld, conditioned or delayed, it has not made and will not make any offer relating to the Placement Shares that would constitute an Issuer Free Writing Prospectus, or that would otherwise constitute a “free writing prospectus,” as defined in Rule 405, required to be filed with the Commission. Any such free writing prospectus consented to by the Agent or by the Company, as the case may be, is hereinafter referred to as a “Permitted Free Writing Prospectus.” The Company represents and warrants that it has treated and agrees that it will treat each Permitted Free Writing Prospectus as an “issuer free writing prospectus,” as defined in Rule 433, and has complied and will comply with the requirements of Rule 433 applicable to any Permitted Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. For the purposes of clarity, the parties hereto agree that all free writing prospectuses, if any, listed in Exhibit 23 hereto are Permitted Free Writing Prospectuses.

24. Absence of Fiduciary Relationship.

The Company acknowledges and agrees that:

(a) the Agent is acting solely as agent in connection with the public offering of the Placement Shares and in connection with each transaction contemplated by this Agreement and the process leading to such transactions, and no fiduciary or advisory relationship between the Company or any of its respective affiliates, stockholders (or other equity holders), creditors or employees or any other party, on the one hand, and the Agent, on the other hand, has been or will be created in respect of any of the transactions contemplated by this Agreement, irrespective of whether or not the Agent has advised or is advising the Company on other matters, and the Agent has no obligation to the Company with respect to the transactions contemplated by this Agreement except the obligations expressly set forth in this Agreement;

(b) it is capable of evaluating and understanding, and understands and accepts, the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) Neither the Agent nor its affiliates have provided any legal, accounting, regulatory or tax advice with respect to the transactions contemplated by this Agreement and it has consulted its own legal, accounting, regulatory and tax advisors to the extent it has deemed appropriate;

(d) it is aware that the Agent and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and the Agent and its affiliates has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship or otherwise; and

(e) it waives, to the fullest extent permitted by law, any claims it may have against the Agent or its affiliates for breach of fiduciary duty or alleged breach of fiduciary duty in connection with the sale of Placement Shares under this Agreement and agrees that the Agent

and its affiliates shall not have any liability (whether direct or indirect, in contract, tort or otherwise) to it in respect of such a fiduciary duty claim or to any person asserting a fiduciary duty claim on its behalf or in right of it or the Company, employees or creditors of the Company, other than in respect of the Agent's obligations under Section 20 of this Agreement to keep information provided by the Company to the Agent and the Agent's counsel confidential, to the extent not otherwise publicly-available.

25. Definitions.

As used in this Agreement, the following terms have the respective meanings set forth below:

**"Applicable Time"** means (i) each Representation Date and (ii) the time of each sale of any Placement Shares pursuant to this Agreement.

**"Issuer Free Writing Prospectus"** means any "issuer free writing prospectus," as defined in Rule 433, relating to the Placement Shares that (1) is required to be filed with the Commission by the Company, (2) is a "road show" that is a "written communication" within the meaning of Rule 433(d)(8)(i) whether or not required to be filed with the Commission, or (3) is exempt from filing pursuant to Rule 433(d)(5)(i) because it contains a description of the Placement Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g) under the Securities Act Regulations.

**"Rule 164," "Rule 172," "Rule 405," "Rule 415," "Rule 424," "Rule 424(b)," "Rule 430B,"** and **"Rule 433"** refer to such rules under the Securities Act Regulations.

All references in this Agreement to financial statements and schedules and other information that is "contained," "included" or "stated" in the Registration Statement or the Prospectus (and all other references of like import) shall be deemed to mean and include all such financial statements and schedules and other information that is incorporated by reference in the Registration Statement or the Prospectus, as the case may be. For purposes of clarity, any financial information that is furnished by the Company shall not be deemed incorporated by reference in the Registration Statement or the Prospectus.

All references in this Agreement to the Registration Statement, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to EDGAR; all references in this Agreement to any Issuer Free Writing Prospectus (other than any Issuer Free Writing Prospectuses that, pursuant to Rule 433, are not required to be filed with the Commission) shall be deemed to include the copy thereof filed with the Commission pursuant to EDGAR; and all references in this Agreement to "supplements" to the Prospectus shall include, without limitation, any supplements, "wrappers" or similar materials prepared in connection with any offering, sale or private placement of any Placement Shares by the Agent outside of the United States.

**[Signature Page Follows]**

If the foregoing correctly sets forth the understanding between the Company and the Agent, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and the Agent.

Very truly yours,

AKEBIA THERAPEUTICS, INC.

By: \_\_\_\_\_

Name:

Title:

ACCEPTED as of the date first-above written:

CANTOR FITZGERALD & CO.

By: \_\_\_\_\_

Name:

Title:

[SIGNATURE PAGE]

AKEBIA THERAPEUTICS, INC. – SALES AGREEMENT

SCHEDULE 1

---

FORM OF PLACEMENT NOTICE

---

From: Akebia Therapeutics, Inc.

To: Cantor Fitzgerald & Co.  
Attention: \_\_\_\_\_

Subject: Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Akebia Therapeutics, Inc., a Delaware corporation (the "**Company**"), and Cantor Fitzgerald & Co. ("**Agent**"), dated [●], 2016, the Company hereby requests that the Agent sell up to \_\_\_\_\_ of the Company's Common Stock, par value \$0.00001 per share, at a minimum market price of \$\_\_\_\_ per share, during the time period beginning [month, day, time] and ending [month, day, time].



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## SCHEDULE 2

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### Compensation

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The Company shall pay to the Agent in cash, upon each sale of Placement Shares pursuant to this Agreement, an amount equal to up to 3.0% of the aggregate gross proceeds from each sale of Placement Shares.

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**SCHEDULE 3**

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**Notice Parties**

---

The Company

John P. Butler (jbutler@akebia.com)

Jason A. Amello (jamello@akebia.com)

Nicole R. Hadas (nhadas@akebia.com)

The Agent

Jeff Lumby (jlumby@cantor.com)

Josh Feldman (jfeldman@cantor.com)

Sameer Vasudev (svasudev@cantor.com)

With copies to:

CFControlledEquityOffering@cantor.com

---

**SCHEDULE 4**

---

**Subsidiaries**

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Akebia Therapeutics Securities Corporation  
Akebia Europe Limited

**EXHIBIT 7(I)**

**Form of Representation Date Certificate**

The undersigned, the duly qualified and elected \_\_\_\_\_, of Akebia Therapeutics, Inc., a Delaware corporation (the "Company"), does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(I) of the Sales Agreement, dated [●], 2016 (the "Sales Agreement"), between the Company and Cantor Fitzgerald & Co., that to the best of the knowledge of the undersigned:

(i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Effect, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; provided, however, that in the case of clauses (A) and (B), such representations and warranties also shall be qualified by the disclosure included or incorporated by reference in the Registration Statement and Prospectus; and

(ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

AKEBIA THERAPEUTICS, INC.

By: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

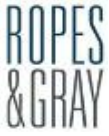
Date: \_\_\_\_\_

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**Exhibit 23**

**Permitted Free Writing Prospectus**

[None.]



ROPES & GRAY LLP  
PRUDENTIAL TOWER  
800 BOYLSTON STREET  
BOSTON, MA 02199-3600  
WWW.ROPESGRAY.COM

May 5, 2016

Akebia Therapeutics, Inc.  
245 First Street, Suite 1100  
Cambridge, MA 02142

Re: Registration of Securities by Akebia Therapeutics, Inc.

Ladies and Gentlemen:

We have acted as counsel to Akebia Therapeutics, Inc., a Delaware corporation (the "Company") in connection with the registration statement on Form S-3 (the "Registration Statement"), filed on the date hereof by the Company with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration under the Securities Act and the proposed issuance and sale from time to time pursuant to Rule 415 under the Securities Act of shares of the Company's common stock, \$0.00001 par value per share (the "Common Stock").

In connection with this opinion letter, we have examined such certificates, documents and records and have made such investigation of fact and such examination of law as we have deemed appropriate in order to enable us to render the opinions set forth herein. In conducting such investigation, we have relied, without independent verification, upon certificates of officers of the Company, public officials and other appropriate persons.

The opinions expressed below are limited to the Delaware General Corporation Law.

Based upon and subject to the foregoing and the assumptions, qualifications and limitations set forth below, we are of the opinion that when (i) the issuance and sale of any shares of the Common Stock have been duly authorized by all necessary corporate action of the Company and (ii) such shares have been issued and delivered against payment of the purchase price therefor (in an amount in excess of the par value thereof) in accordance with the applicable purchase, underwriting or other agreement, and as contemplated by the Registration Statement, such shares of Common Stock will be validly issued, fully paid and nonassessable.

In rendering the opinion set forth above, we have assumed that (i) the Registration Statement will have become effective under the Securities Act, a prospectus supplement will have been prepared and filed with the Commission describing the Common Stock offered thereby and such Common Stock will have been issued and sold in accordance with the terms of such prospectus supplement; (ii) a definitive purchase, underwriting, or similar agreement, pursuant to which the Common Stock may be issued, will have been duly authorized, executed and delivered by the Company and the other parties thereto; (iii) at the time of the issuance of the Common Stock, the Company will be a validly existing corporation under the law of its

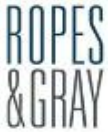
jurisdiction of incorporation; (iv) the number of shares of Common Stock issued pursuant to the Registration Statement, together with the number of shares outstanding or reserved at the time of issuance, will not exceed the respective number of shares authorized by the Company's certificate of incorporation in effect at the time of such issuance; and (v) all the foregoing actions to be taken by the Company will have been taken so as not to violate any applicable law and so as to comply with any requirement or restriction imposed by any court or governmental or regulatory body having jurisdiction over the Company or any of its property.

We hereby consent to the filing of this opinion letter as an exhibit to the Registration Statement and to the use of our name therein and in the related prospectus under the caption "Legal Matters." In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Ropes & Gray LLP

Ropes & Gray LLP



ROPES & GRAY LLP  
PRUDENTIAL TOWER  
800 BOYLSTON STREET  
BOSTON, MA 02199-3600  
WWW.ROPESGRAY.COM

May 5, 2016

Akebia Therapeutics, Inc.  
245 First Street, Suite 1100  
Cambridge, MA 02142

Re: Registration of Securities by Akebia Therapeutics, Inc.

Ladies and Gentlemen:

We have acted as counsel to Akebia Therapeutics, Inc., a Delaware corporation (the "Company") in connection with its filing of a Registration Statement on Form S-3 (the "Registration Statement"), with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Securities Act"), relating to the sale of up to \$75,000,000 of shares (the "Shares") of the common stock, \$0.00001 par value (the "Common Stock"), of the Company. The Shares are being sold pursuant to a Controlled Equity Offering Sales Agreement, dated May 5, 2016, by and between the Company and Cantor Fitzgerald & Co. (the "Agreement"), pursuant to which the Company may issue and sell the Shares pursuant to the Registration Statement and the accompanying prospectus.

In connection with this opinion letter, we have examined such certificates, documents and records and have made such investigation of fact and such examination of law as we have deemed appropriate in order to enable us to render the opinions set forth herein. In conducting such investigation, we have relied, without independent verification, upon certificates of officers of the Company, public officials and other appropriate persons.

The opinion expressed below is limited to the Delaware General Corporation Law.

Based upon and subject to the foregoing, we are of the opinion that, when the Shares are issued out of the Company's duly authorized Common Stock and issued and delivered in accordance with the terms of the Agreement against payment of the consideration set forth therein, on terms approved by the Pricing Committee of the Board of Directors of the Company, the Shares will be validly issued, fully paid and non-assessable.

We hereby consent to your filing this opinion as an exhibit to the Registration Statement and to the use of our name therein and in the related prospectus under the caption "Legal Matters." In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Sections 7 of the Securities Act or the rules and regulations of the Commission thereunder.



Very truly yours,

/s/ Ropes & Gray LLP

Ropes & Gray LLP

**Consent of Independent Registered Public Accounting Firm**

We consent to the reference of our firm under the caption “Experts” in the Registration Statement (Form S-3) and related Prospectuses of Akebia Therapeutics, Inc. for the registration of up to \$175,000,000 of common stock and to the incorporation by reference therein of our report dated March 14, 2016, with respect to the consolidated financial statements of Akebia Therapeutics, Inc. included in its Annual Report (Form 10-K) for the year ended December 31, 2015, filed with the Securities and Exchange Commission.

/s/ Ernst & Young LLP

Boston, Massachusetts

May 5, 2016