UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 6, 2016

AKEBIA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-36352 (Commission File Number) 20-8756903 (IRS Employer Identification No.)

245 First Street, Suite 1100, Cambridge, Massachusetts 02142 (Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (617) 871-2098

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

□ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01. Entry into a Material Definitive Agreement

On January 6, 2016, Akebia Therapeutics, Inc. (the "<u>Company</u>") entered into an underwriting agreement (the "<u>Underwriting Agreement</u>") with Morgan Stanley & Co. LLC and UBS Securities LLC as representatives of the several underwriters listed on Schedule II thereto (the "<u>Underwriters</u>"), related to a public offering (the "<u>Offering</u>") of 7,250,000 shares of the Company's common stock, \$0.00001 par value per share, (the "<u>Common Stock</u>") at a price to the public of \$9.00 per share pursuant to a registration statement on Form S-3 (File No. 333-203206) and a related prospectus supplement. In addition, the Company granted the Underwriters an option to purchase, at the public offering price less any underwriting discounts and commissions, an additional 1,087,500 shares of Common Stock exercisable for 30 days from the date of the Underwriting Agreement. Subject to customary closing conditions, the Offering is expected to close on January 12, 2016.

The above description of the Underwriting Agreement is qualified in its entirety by reference to the Underwriting Agreement, which is filed as Exhibit 1.1 hereto and incorporated herein by reference.

An opinion dated January 12, 2016 regarding the legality of the issuance and sale of the Common Stock in the Offering is filed as Exhibit 5.1 to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit No.	Description
1.1	Underwriting Agreement, dated January 6, 2016, by and among Akebia Therapeutics, Inc. and Morgan Stanley & Co. LLC and UBS Securities LLC, as representatives of the several underwriters listed on Schedule II thereto.
5.1	Opinion of Ropes & Gray LLP.

23.1 Consent of Ropes & Gray LLP (included in Exhibit 5.1 above).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AKEBIA THERAPEUTICS, INC.

/s/ John P. Butler

Name: John P. Butler Title: President and Chief Executive Officer

Date: January 12, 2016

EXHIBIT INDEX

Description

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Exhibit No.

23.1 Consent of Ropes & Gray LLP (included in Exhibit 5.1 above).

7,250,000 Shares

AKEBIA THERAPEUTICS, INC.

COMMON STOCK, PAR VALUE \$0.00001 PER SHARE

UNDERWRITING AGREEMENT

January 6, 2016

To the Representatives named in Schedule I hereto

For the Underwriters named in Schedule II hereto

Ladies and Gentlemen:

Akebia Therapeutics, Inc., a Delaware corporation (the "**Company**"), proposes to issue and sell to the several underwriters named in Schedule II hereto (the "**Underwriters**"), for whom you are acting as representatives (the "**Representatives**") the number of shares of its common stock, par value \$0.00001 per share, set forth in Schedule I hereto (the "**Firm Shares**"). The Company also proposes to issue and sell to the several Underwriters not more than the number of additional shares of its common stock, par value \$0.00001 per share, set forth in Schedule I hereto (the "**Additional Shares**") if and to the extent that you, as Representatives of the Underwriters, shall have determined to exercise, on behalf of the Underwriters, the right to purchase such shares of common stock granted to the Underwriters in Section 2 hereof. The Firm Shares and the Additional Shares are hereinafter collectively referred to as the "**Shares**." The shares of common stock, par value \$0.00001 per share, of the Company to be outstanding after giving effect to the sales contemplated hereby are hereinafter referred to as the "**Common Stock**." If the firm or firms listed in Schedule II hereto include only the Representatives listed in Schedule I hereto, then the terms "Underwriters" and "Representatives" as used herein shall each be deemed to refer to such firm or firms.

The Company has filed with the Securities and Exchange Commission (the "**Commission**") a registration statement, including a prospectus, (the file number of which is set forth in Schedule I hereto) on Form S-3, relating to the securities (the "**Shelf Securities**"), including the Shares, to be issued from time to time by the Company. The registration statement as amended to the date of this Agreement, including the information (if any) deemed to be part of the registration statement at the time of effectiveness pursuant to Rule 430A or Rule 430B under the Securities Act of 1933, as amended (the "**Securities Act**"), is hereinafter referred to as the "**Registration Statement**" and the related prospectus covering the Shelf Securities dated April 14, 2015 in the form first used to confirm sales of the Shares (or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 462(b) under the Securities Act, (the "**Rule 462 Registration Statement**"), then any reference herein to the term "Registration Statement" shall be deemed to include such Rule 462 Registration Statement. The Basic Prospectus, as supplemented by the prospectus supplement specifically relating to the Shares in the form first used to confirm sales of the Shares (or in the form first used to confirm sales of the Shares of purchasers pursuant to Rule 462 Registration Statement"), then any reference herein to the term "Registration Statement" shall be deemed to include such Rule 462 Registration Statement. The Basic Prospectus, as supplemented by the prospectus supplement specifically relating to the Shares in the form first used to confirm sales of the Shares (or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act) is hereinafter referred to as the "Prospectus," and the

term "**preliminary prospectus**" means any preliminary form of the Prospectus. For purposes of this Agreement, "**free writing prospectus**" has the meaning set forth in Rule 405 under the Securities Act, "**Time of Sale Prospectus**" means the documents and pricing information set forth opposite the caption "Time of Sale Prospectus" in Schedule I hereto, and "**broadly available road show**" means a "bona fide electronic road show" as defined in Rule 433(h)(5) under the Securities Act that has been made available without restriction by means of graphic communication to any person. As used herein, the terms "Registration Statement," "Basic Prospectus," "preliminary prospectus," "Time of Sale Prospectus" and "Prospectus" shall include the documents, if any, incorporated by reference therein as of the date hereof. The terms "**supplement**," "**amendment**," and "**amend**" as used herein with respect to the Registration Statement, the Basic Prospectus, the Time of Sale Prospectus, any preliminary prospectus or the Prospectus shall include all documents subsequently filed by the Company with the Commission pursuant to the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), that are deemed to be incorporated by reference therein.

1. Representations and Warranties. The Company represents and warrants to and agrees with each of the Underwriters that:

(a) The Registration Statement has become effective; no stop order suspending the effectiveness of the Registration Statement is in effect, and no proceedings for such purpose are pending before or threatened by the Commission. If the Registration Statement is an automatic shelf registration statement as defined in Rule 405 under the Securities Act, the Company is a well-known seasoned issuer (as defined in Rule 405 under the Securities Act) eligible to use the Registration Statement as an automatic shelf registration statement and the Company has not received notice that the Commission objects to the use of the Registration Statement as an automatic shelf registration statement.

(b) (i) Each document, if any, filed or to be filed pursuant to the Exchange Act and incorporated by reference in the Time of Sale Prospectus or the Prospectus complied or will comply when so filed in all material respects with the Exchange Act and the applicable rules and regulations of the Commission thereunder, (ii) each part of the Registration Statement, when such part became effective, did not contain, and each such part, as amended or supplemented, if applicable, will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (iii) the Registration Statement as of the date hereof does not contain any untrue statement and the Prospectus comply, and as amended or supplemented, if applicable, will comply in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder, (v) the Time of Sale Prospectus does not, and at the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers and at the Closing Date (as defined in Section 4), the Time of Sale Prospectus, as then amended or

supplemented by the Company, if applicable, will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, (vi) each broadly available road show, if any, when considered together with the Time of Sale Prospectus, does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading and (vii) the Prospectus does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading and (vii) the Prospectus does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, except that the representations and warranties set forth in this paragraph do not apply to statements or omissions in the Registration Statement, the Time of Sale Prospectus or the Prospectus based upon information relating to any Underwriter furnished to the Company in writing by such Underwriter through the Representatives expressly for use therein.

(c) The Company is not an "ineligible issuer" in connection with the offering pursuant to Rules 164, 405 and 433 under the Securities Act. Any free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of the Securities Act and the applicable rules and regulations of the Commission thereunder. Except for the free writing prospectuses, if any, identified in Schedule I hereto forming part of the Time of Sale Prospectus, and electronic road shows, if any, each furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior consent, prepare, use or refer to, any free writing prospectus.

(d) The Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own its property and to conduct its business as described in the Time of Sale Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent that the failure to be so qualified or be in good standing would not have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(e) Each subsidiary of the Company has been duly incorporated, is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation, has the corporate power and authority to own its property and to conduct its business as described in the Time of Sale Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which the conduct of its business or its ownership or leasing of property requires such qualification, except to the extent

that the failure to be so qualified or be in good standing would not have a material adverse effect on the Company and its subsidiaries, taken as a whole; all of the issued shares of capital stock of each subsidiary of the Company have been duly and validly authorized and issued, are fully paid and non-assessable and are owned directly by the Company, free and clear of all liens, encumbrances, equities or claims.

(f) This Agreement has been duly authorized, executed and delivered by the Company.

(g) The authorized capital stock of the Company conforms as to legal matters to the description thereof contained in each of the Time of Sale Prospectus and the Prospectus.

(h) The shares of Common Stock outstanding prior to the issuance of the Shares have been duly authorized and are validly issued, fully paid and non-assessable.

(i) The Shares have been duly authorized and, when issued and delivered in accordance with the terms of this Agreement, will be validly issued, fully paid and non-assessable, and the issuance of such Shares will not be subject to any preemptive or similar rights that have not been waived.

(j) The execution and delivery by the Company of, and the performance by the Company of its obligations under, this Agreement will not contravene any provision of applicable law or the certificate of incorporation or by-laws of the Company or any agreement or other instrument binding upon the Company or any of its subsidiaries that is material to the Company and its subsidiaries, taken as a whole, or any judgment, order or decree of any governmental body, agency or court having jurisdiction over the Company or any subsidiary, and no consent, approval, authorization or order of, or qualification with, any governmental body or agency is required for the performance by the Company of its obligations under this Agreement, except such as may be required by the securities or Blue Sky laws of the various states in connection with the offer and sale of the Shares.

(k) There has not occurred any material adverse change, or any development involving a prospective material adverse change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company and its subsidiaries, taken as a whole, from that set forth in the Time of Sale Prospectus.

(1) There are no legal or governmental proceedings pending or threatened to which the Company or any of its subsidiaries is a party or to which any of the properties of the Company or any of its subsidiaries is subject (i) other than proceedings accurately described in all material respects in the Time of Sale Prospectus and proceedings that would not reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole, or on the power or ability of the Company to perform its obligations under this Agreement or (ii) that are required to be described in the Registration Statement or the Prospectus and are not so described; and there are no statutes, regulations, contracts or other documents that are required to be described in the Registration Statement or the Prospectus or to be filed as exhibits to the Registration Statement that are not described or filed as required.

(m) Each preliminary prospectus filed pursuant to Rule 424 under the Securities Act, complied when so filed in all material respects with the Securities Act and the applicable rules and regulations of the Commission thereunder.

(n) The Company is not, and after giving effect to the offering and sale of the Shares and the application of the proceeds thereof as described in the Prospectus will not be, required to register as an "investment company" as such term is defined in the Investment Company Act of 1940, as amended.

(o) The Company and its subsidiaries (i) are in compliance with any and all applicable foreign, federal, state and local laws and regulations relating to the protection of human health and safety, the environment or hazardous or toxic substances or wastes, pollutants or contaminants ("**Environmental Laws**"), (ii) have received all permits, licenses or other approvals required of them under applicable Environmental Laws to conduct their respective businesses and (iii) are in compliance with all terms and conditions of any such permit, license or approval, except where such noncompliance with Environmental Laws, failure to receive required permits, licenses or other approvals or failure to comply with the terms and conditions of such permits, licenses or approvals would not, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(p) There are no costs or liabilities associated with Environmental Laws (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or any permit, license or approval, any related constraints on operating activities and any potential liabilities to third parties) which would, singly or in the aggregate, reasonably be expected to have a material adverse effect on the Company and its subsidiaries, taken as a whole.

(q) There are no contracts, agreements or understandings between the Company and any person granting such person the right to require the Company to file a registration statement under the Securities Act with respect to any securities of the Company or to require the Company to include such securities with the Shares registered pursuant to the Registration Statement that have not been waived.

(r) Neither the Company nor any of its subsidiaries or affiliates, nor any director, officer, or employee, nor, to the Company's knowledge, any agent or representative of the Company or of any of its subsidiaries or affiliates, has taken or will take any action in furtherance of an offer, payment, promise to pay, or authorization or approval of the payment or giving of money, property, gifts or anything else of value, directly or indirectly, to any "government official" (including any officer or employee of a government or government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the

foregoing, or any political party or party official or candidate for political office) to influence official action or secure an improper advantage; and the Company and its subsidiaries and affiliates have conducted their businesses in compliance with applicable anti-corruption laws and have instituted and maintain policies and procedures designed to promote and achieve compliance with such laws and with the representation and warranty contained herein.

(s) The operations of the Company and its subsidiaries are and have been conducted at all times in material compliance with all applicable financial recordkeeping and reporting requirements, including those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of jurisdictions where the Company and its subsidiaries conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Anti-Money Laundering Laws**"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(t) (i) Neither the Company nor any of its subsidiaries, nor any director, officer, or employee thereof, nor, to the Company's knowledge, any agent, affiliate or representative of the Company or any of its subsidiaries, is an individual or entity ("**Person**") that is, or is owned or controlled by a Person that is:

(A) the subject of any sanctions administered or enforced by the U.S. Department of Treasury's Office of Foreign Assets Control ("**OFAC**"), the United Nations Security Council ("**UNSC**"), the European Union ("**EU**"), Her Majesty's Treasury ("**HMT**"), or other relevant sanctions authority (collectively, "**Sanctions**"), nor

(B) located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, Crimea, Cuba, Iran, North Korea, Sudan and Syria).

(ii) The Company will not, directly or indirectly, use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other Person:

(A) to fund or facilitate any activities or business of or with any Person or in any country or territory that, at the time of such funding or facilitation, is the subject of Sanctions; or

(B) in any other manner that will result in a violation of Sanctions by any Person (including any Person participating in the offering, whether as underwriter, advisor, investor or otherwise).

(iii) For the past 5 years, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(u) Subsequent to the respective dates as of which information is given in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, (i) the Company and its subsidiaries have not incurred any material liability or obligation, direct or contingent, nor entered into any material transaction; (ii) the Company and its subsidiaries have not purchased any of its outstanding capital stock, nor declared, paid or otherwise made any dividend or distribution of any kind on its capital stock other than ordinary and customary dividends; and (iii) there has not been any material change in the capital stock, short-term debt or long-term debt of the Company or its subsidiaries, except in each case as described in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus, respectively.

(v) The Company and its subsidiaries do not own any real property. The Company and its subsidiaries have good and marketable title to all personal property owned by them which is material to the business of the Company, in each case free and clear of all liens, encumbrances and defects except such as are described in the Time of Sale Prospectus or such as do not materially affect the value of such property and do not interfere with the use made and proposed to be made of such property by the Company or its subsidiaries; and any real property and buildings held under lease by the Company or its subsidiaries are held by it under valid, subsisting and enforceable leases with such exceptions as would not reasonably be expected to have a material adverse effect on the Company, except as described in the Time of Sale Prospectus.

(w) The Company and its subsidiaries own or are licensed rights to, or otherwise have rights to exploit, all Intellectual Property (as defined below) necessary for the conduct of the Company's business as now currently conducted or as currently proposed to be conducted by it in the future as disclosed in the Time of Sale Prospectus, except as disclosed in the Time of Sale Prospectus or except as would not reasonably be expected to have a material adverse effect on the Company. There is no infringement, misappropriation or violation, or the occurrence of any event that with notice or the passage of time would constitute any of the foregoing, (i) by third parties of any Intellectual Property owned by or licensed to the Company or any of its subsidiaries or (ii) by the Company or any of its subsidiaries of any Intellectual Property of any third parties, in each case, except as disclosed in the Time of Sale Prospectus or except as would not reasonably be expected to have a material adverse effect on the Company. There is no pending, or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others to which the Company or any of its subsidiaries is a party

or otherwise, challenging the Company's or any of its subsidiaries' rights in or to, or exploitation of, any such Intellectual Property, except as disclosed in the Time of Sale Prospectus. Such Intellectual Property owned by the Company and its subsidiaries and, to the knowledge of the Company, such Intellectual Property licensed to the Company and its subsidiaries have not been adjudged invalid or unenforceable, in whole or in part, and there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any such Intellectual Property, except as disclosed in the Time of Sale Prospectus. There is no pending, or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others that the Company or its subsidiaries infringes, misappropriates or otherwise violates any Intellectual Property or other proprietary rights of others, the Company and its subsidiaries have not received any written notice of such claim and the Company has no knowledge of any other fact which would form a reasonable basis for any such claim. The Company and its subsidiaries have complied with the terms of each agreement pursuant to which any Intellectual Property has been licensed to the Company and its subsidiaries, and all such agreements are in full force and effect, except as would not reasonably be expected to have a material adverse effect. None of the Intellectual Property used by the Company or its subsidiaries in its business has been obtained or is being used by the Company or its subsidiaries in violation of any contractual obligation binding on the Company or its subsidiaries. No employee or independent contractor of the Company or its subsidiaries is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer or independent contractor where the basis of such violation relates to such employee's employment or independent contractor's engagement with the Company or its subsidiaries or actions undertaken while employed or engaged with the Company or its subsidiaries, except as disclosed in the Time of Sale Prospectus. "Intellectual Property" shall mean all patents, patent rights, trade and service marks, trade names, copyrights, licenses, inventions, trade secrets, domain names, and registrations and applications for registration thereof.

(x) No material labor dispute with the employees of the Company and its subsidiaries exists, except as described in the Time of Sale Prospectus, or, to the knowledge of the Company, is imminent; and the Company and its subsidiaries are not aware of any existing, threatened or imminent labor disturbance by the employees of any of its principal suppliers, manufacturers or contractors that would reasonably be expected to have a material adverse effect on the Company or its subsidiaries, taken as a whole.

(y) The Company and its subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as management of the Company reasonably believes are prudent and customary in the businesses in which they are engaged; neither the Company nor any of its subsidiaries has been refused any insurance coverage sought or applied for; and the Company and its subsidiaries have no reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage is scheduled to expire or to obtain similar coverage from similar

insurers as may be necessary to continue its business at a cost that would not have a material adverse effect on the Company, except as described in the Time of Sale Prospectus.

(z) Neither the Company nor any of its subsidiaries have received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the U.S. Food and Drug Administration ("FDA") or any similar regulatory authority alleging or asserting noncompliance by the Company or its subsidiaries. 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.

(aa) The Company and its subsidiaries, and to the Company's knowledge, its respective directors, officers, employees, agents, affiliates and representatives, are, and at all times have been, in compliance in all material respects with all health care laws applicable to the Company or its subsidiaries or any of their respective products or activities, including, but not limited to, the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the civil False Claims Act (31 U.S.C. §§3729 et seq.), the administrative False Claims Law (42 U.S.C. § 1320a-7b(a)), the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. §§ 17921 et seq.), the exclusion laws (42 U.S.C. § 1320a-7), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), the Public Health Service Act (42 U.S.C. § 201 et seq.), any similar local, state or federal laws, and the regulations promulgated pursuant to such laws (collectively, the "**Health Care Laws**"), and have not engaged in activities which are, as applicable, prohibited or cause for civil penalties or mandatory or permissive exclusion from Medicare, Medicaid, or any other state health care program or federal health care program. The Company 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 Health Care Laws.

(bb) The Company and its subsidiaries possess, and are in compliance in all material respects with the terms of, all certificates, approvals, clearances, registrations, exemptions, franchises, licenses, permits and other authorizations necessary to conduct their respective businesses (collectively, "Licenses"), including, without limitation, all Licenses required by the FDA and/or by any other U.S., state, local or foreign government or drug regulatory agency (collectively, the "**Regulatory Agencies**"). All Licenses are in full force and effect and the Company and its subsidiaries are not in violation of any term of any License in any material respect. The Company and its

subsidiaries have fulfilled and performed all of their obligations in all material respects with respect to the Licenses and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the holder of any License. Neither the Company nor any of its subsidiaries have received any notice of proceedings relating to the revocation or modification of any Licenses that, if determined adversely to the Company or its subsidiaries, would reasonably be expected to have a material impact on the Company. To the Company's knowledge, no Regulatory Agency has taken any action to limit, suspend or revoke any License possessed by the Company or its subsidiaries.

(cc) The preclinical tests and clinical trials that are described in, or the results of which are referred to in, the Time of Sale Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols established for each such preclinical test or clinical trial and all Health Care Laws, including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58 and 312, and, where applicable, the EU Clinical Trials Directive (Directive 2001/20/EC) as implemented; each description of such tests and trials, and the results thereof, contained in the Time of Sale Prospectus is accurate and complete in all material respects and fairly presents the data about and derived from such tests and trials, and neither the Company nor any of its subsidiaries have knowledge of any other studies or tests the results of which call into question, the results described or referred to in the Time of Sale Prospectus; and neither the Company nor any of its subsidiaries have received any notices or other correspondence from FDA or any similar regulatory authority requiring the termination, suspension or material modification of any preclinical tests or clinical trials that are, or whose results of which are, described or referred to in the Time of Sale Prospectus.

(dd) Neither the Company nor, to the Company's knowledge, any of its respective subsidiaries, directors, officers, employees and agents, is debarred, suspended or excluded, or has been convicted of any crime or engaged in any conduct that could result in a debarment, suspension or exclusion, from any federal or state government health care program under 21 U.S.C. § 335a or any other Health Care Law. No claims, actions, proceedings or investigations that would reasonably be expected to result in such a debarment, suspension or exclusion are pending or, to the Company's knowledge, threatened against the Company, or the subsidiaries, directors, officers, employees or agents of the Company.

(ee) The Company and each of its subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken

with respect to any differences. Except as described in the Time of Sale Prospectus, since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness in the Company's internal control over financial reporting (whether or not remediated) identified by the Company and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

(ff) Except as described in the Time of Sale Prospectus, neither the Company nor any of its subsidiaries have sold, issued or distributed any shares of Common Stock during the six-month period preceding the date hereof, including any sales pursuant to Rule 144A under, or Regulation D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock option plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.

(gg) The Company and its subsidiaries have filed all federal, state, local and foreign tax returns required to be filed through the date of this Agreement or have requested extensions thereof (except where the failure to file would not, individually or in the aggregate, reasonably be expected to have a material adverse effect) and have paid all taxes required to be paid thereon (except for cases in which the failure to pay would not have a material adverse effect, or, except as currently being contested in good faith and for which adequate reserves required by U.S. GAAP have been created in the financial statements of the Company and its subsidiaries), and no tax deficiency has been determined adversely to the Company or any of its subsidiaries which has, individually or in the aggregate, had (nor do the Company or any of its subsidiaries have any notice or knowledge of any tax deficiency which would reasonably be expected to be determined adversely to the Company or its subsidiaries and which would reasonably be expected to, individually or in the aggregate, have) a material adverse effect on the Company or its subsidiaries, taken as a whole.

(hh) The interactive data in eXtensible Business Reporting Language included or incorporated by reference in the Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.

(ii) From the time of initial filing of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**"). "**Testing-the-Waters Communication**" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

(jj) The Company and its subsidiaries (i) have not alone engaged in any Testing-the-Waters Communication and (ii) have not authorized anyone to engage in

Testing-the-Waters Communications. Neither the Company nor any of its subsidiaries have distributed any Written Testing-the-Waters Communications other than those listed on Schedule III hereto. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

(kk) As of the time of each sale of the Shares in connection with the offering when the Prospectus is not yet available to prospective purchasers, none of (i) the Time of Sale Prospectus, (ii) any free writing prospectus, when considered together with the Time of Sale Prospectus, and (iii) any individual Written Testing-the-Waters Communication, when considered together with the Time of Sale Prospectus, included or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

2. Agreements to Sell and Purchase. The Company hereby agrees to sell to the several Underwriters, and each Underwriter, upon the basis of the representations and warranties herein contained, but subject to the conditions hereinafter stated, agrees, severally and not jointly, to purchase from the Company the respective numbers of Firm Shares set forth in Schedule II hereto opposite its name at the purchase price set forth in Schedule I hereto (the "**Purchase Price**").

On the basis of the representations and warranties contained in this Agreement, and subject to its terms and conditions, the Company agrees to sell to the Underwriters the Additional Shares, and the Underwriters shall have the right to purchase, severally and not jointly, up to the number of Additional Shares set forth in Schedule I hereto at the Purchase Price, provided, however, that the amount paid by the Underwriters for any Additional Shares shall be reduced by an amount per share equal to any dividends declared by the Company and payable on the Firm Shares but not payable on such Additional Shares. You may exercise this right on behalf of the Underwriters in whole or from time to time in part by giving written notice not later than 30 days after the date of the Prospectus. Any exercise notice shall specify the number of Additional Shares to be purchased by the Underwriters and the date on which such shares are to be purchased. Each purchase date must be at least one business day after the written notice is given and may not be earlier than the closing date for the Firm Shares nor later than ten business days after the date of such notice. Additional Shares may be purchased as provided in Section 4 hereof solely for the purpose of covering sales of shares in excess of the number of the Firm Shares. On each day, if any, that Additional Shares are to be purchased (an "**Option Closing Date**"), each Underwriter agrees, severally and not jointly, to purchase the number of Additional Shares to be purchased on such Option Closing Date as the number of Firm Shares set forth in Schedule II hereto opposite the name of such Underwriter bears to the total number of Firm Shares.

3. *Public Offering*. The Company is advised by you that the Underwriters propose to make a public offering of their respective portions of the Shares as soon after the Registration Statement and this Agreement have become effective as in your judgment is advisable. The Company is further advised by you that the Shares are to be offered to the public upon the terms set forth in the Prospectus.

4. *Payment and Delivery*. Payment for the Firm Shares shall be made to the Company in Federal or other funds immediately available in New York City on the closing date and time set forth in Schedule I hereto, or at such other time on the same or such other date, not later than the fifth business day thereafter, as shall be mutually agreed in writing by you and the Company. The time and date of such payment are hereinafter referred to as the "**Closing Date**."

Payment for any Additional Shares shall be made to the Company in Federal or other funds immediately available in New York City on the date specified in the corresponding notice described in Section 2 or at such other time on the same or on such other date, in any event not later than the fifth business day thereafter, as may be mutually agreed in writing by you and the Company.

The Firm Shares and the Additional Shares shall be registered in such names and in such denominations as you shall request in writing not later than one full business day prior to the Closing Date or the applicable Option Closing Date, as the case may be, for the respective accounts of the several Underwriters, with any transfer taxes payable in connection with the transfer of the Shares to the Underwriters duly paid, against payment of the Purchase Price therefor.

5. Conditions to the Underwriters' Obligations. The several obligations of the Underwriters are subject to the following conditions:

(a) Subsequent to the execution and delivery of this Agreement and prior to the Closing Date:

(i) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any of the securities of the Company or any of its subsidiaries by any "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Exchange Act of 1934; and

(ii) there shall not have occurred any change, or any development involving a prospective change, in the condition, financial or otherwise, or in the earnings, business or operations of the Company and its subsidiaries, taken as a whole, from that set forth in the Time of Sale Prospectus that, in your judgment, is material and adverse and that makes it, in your judgment, impracticable to market the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus.

(b) The Underwriters shall have received on the Closing Date a certificate, dated the Closing Date and signed by an executive officer of the Company, to the effect set forth in Section 5(a)(i) above and to the effect that the representations and warranties of the Company contained in this Agreement are true and correct as of the Closing Date and that the Company has complied in all material respects with all of the agreements and satisfied all of the conditions on its part to be performed or satisfied hereunder on or before the Closing Date.

The officer signing and delivering such certificate may rely upon the best of his or her knowledge as to proceedings threatened.

(c) The Underwriters shall have received on the Closing Date an opinion and negative assurance letter of Ropes & Gray LLP, outside counsel for the Company, dated the Closing Date, in form and substance satisfactory to the Representatives.

(d) The Underwriters shall have received on the Closing Date an opinion of Jones Day LLP, intellectual property counsel for the Company, dated the Closing Date, in form and substance satisfactory to the Representatives.

(e) The Underwriters shall have received on the Closing Date an opinion of Latham & Watkins LLP, counsel for the Underwriters, dated the Closing Date, in form and substance satisfactory to the Representatives.

The opinion of Ropes & Gray LLP described in Section 5(c) above and the opinion of Jones Day LLP described in Section 5(d) above shall be rendered to the Underwriters at the request of the Company and shall so state therein.

(f) The Underwriters shall have received, on each of the date hereof and the Closing Date, a letter dated the date hereof or the Closing Date, as the case may be, in form and substance satisfactory to the Underwriters, from Ernst & Young LLP, independent public accountants, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus; *provided* that the letter delivered on the Closing Date shall use a "cut-off date" not earlier than the date hereof.

(g) The "lock-up" agreements, each substantially in the form of Exhibit A hereto, between you and certain shareholders, officers and directors of the Company relating to sales and certain other dispositions of shares of Common Stock or certain other securities listed on Schedule III, delivered to you on or before the date hereof, shall be in full force and effect on the Closing Date.

(h) The several obligations of the Underwriters to purchase Additional Shares hereunder are subject to the delivery to you on the applicable Option Closing Date of the following:

(i) a certificate, dated the Option Closing Date and signed by an executive officer of the Company, confirming that the certificate delivered on the Closing Date pursuant to Section 5(b) hereof remains true and correct as of such Option Closing Date;

(ii) an opinion of Ropes & Gray LLP, outside counsel for the Company, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(c) hereof;

(iii) an opinion of Jones Day LLP, intellectual property counsel for the Company, dated the Option Closing Date, to the same effect as the opinion required by Section 5(d) hereof;

(iv) an opinion of Latham & Watkins LLP, counsel for the Underwriters, dated the Option Closing Date, relating to the Additional Shares to be purchased on such Option Closing Date and otherwise to the same effect as the opinion required by Section 5(e) hereof;

(v) a letter dated the Option Closing Date, in form and substance satisfactory to the Underwriters, from Ernst & Young LLP, independent public accountants, substantially in the same form and substance as the letter furnished to the Underwriters pursuant to Section 5(f) hereof; *provided* that the letter delivered on the Option Closing Date shall use a "cut-off date" not earlier than three business days prior to such Option Closing Date; and

(vi) such other documents as you may reasonably request with respect to the good standing of the Company, the due authorization and issuance of the Additional Shares to be sold on such Option Closing Date and other matters related to the issuance of such Additional Shares.

6. Covenants of the Company. The Company covenants with each Underwriter as follows:

(a) To furnish to you, without charge, a signed copy of the Registration Statement (including exhibits thereto and documents incorporated by reference therein) and to deliver to each of the Underwriters during the period mentioned in Section 6(e) or 6(f) below, as many copies of the Time of Sale Prospectus, the Prospectus, any documents incorporated by reference therein and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) Before amending or supplementing the Registration Statement, or the Time of Sale Prospectus or the Prospectus, in each case prior to the 30th day after the date of the Prospectus, to furnish to you a copy of each such proposed amendment or supplement and not to file any such proposed amendment or supplement to which you reasonably object, and to file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) To furnish to you a copy of each proposed free writing prospectus to be prepared by or on behalf of, used by, or referred to by the Company and not to use or refer to any proposed free writing prospectus to which you reasonably object.

(d) Not to take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of the Underwriter that the Underwriter otherwise would not have been required to file thereunder.

(e) If the Time of Sale Prospectus is being used to solicit offers to buy the Shares at a time when the Prospectus is not yet available to prospective purchasers and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus in order to make the statements therein, in the light of the circumstances, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement then on file, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not, in the light of the circumstances when the Time of Sale Prospectus is delivered to a prospective purchaser, be misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) If, during such period after the first date of the public offering of the Shares as in the opinion of counsel for the Underwriters the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is required by law to be delivered in connection with sales by an Underwriter or dealer, any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus in order to make the statements therein, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, not misleading, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Prospectus to comply with applicable law, forthwith to prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to the dealers (whose names and addresses you will furnish to the Company) to which Shares may have been sold by you on behalf of the Underwriters and to any other dealers upon request, either amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not, in the light of the circumstances when the Prospectus (or in lieu thereof the notice referred to in Rule 173(a) of the Securities Act) is delivered to a purchaser, sa mended or supplemented, will comply with applicable law.

(g) To endeavor to qualify the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions as you shall reasonably request.

(h) To make generally available to the Company's security holders and to you as soon as practicable an earning statement covering a period of at least twelve months beginning with the first fiscal quarter of the Company occurring after the date of this Agreement which shall satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(i) Whether or not the transactions contemplated in this Agreement are consummated or this Agreement is terminated, to pay or cause to be paid all expenses incident to the performance of the Company's obligations under this Agreement, including: (i) the fees, disbursements and expenses of the Company's counsel and the Company's accountants in connection with the registration and delivery of the Shares under the Securities Act and all other fees or expenses incurred by the Company in connection with the preparation and filing of the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company and amendments and supplements to any of the foregoing, including the filing fees payable to the Commission relating to the Shares (within the time required by Rule 456(b)(1), if applicable), all printing costs associated therewith, and the mailing and delivering of copies thereof to the Underwriters and dealers, in the quantities hereinabove specified, (ii) all costs and expenses related to the transfer and delivery of the Shares to the Underwriters, including any transfer or other taxes payable thereon, (iii) the cost of printing or producing any Blue Sky or Legal Investment memorandum in connection with the offer and sale of the Shares under state securities laws and all expenses in connection with the qualification of the Shares for offer and sale under state securities laws as provided in Section 6(g) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriters in connection with such qualification and in connection with the Blue Sky or Legal Investment memorandum, (iv) all filing fees and the reasonable fees and disbursements of counsel to the Underwriters incurred in connection with the review and qualification of the offering of the Shares by the Financial Industry Regulatory Authority, (v) all costs and expenses incident to listing the Shares on the NASDAQ Global Market, (vi) the cost of printing certificates representing the Shares, (vii) the costs and charges of any transfer agent, registrar or depositary, (viii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the offering of the Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, travel and lodging expenses of the representatives and officers of the Company and any such consultants, (ix) the

document production charges and expenses associated with printing this Agreement, and (x) all other costs and expenses incident to the performance of the obligations of the Company hereunder for which provision is not otherwise made in this Section; provided that the amount payable by the Company for related reasonable fees and disbursements of counsel to the Underwriters pursuant to the foregoing clauses (iii) and (iv) shall not exceed in the aggregate \$20,000. It is understood, however, that except as provided in this Section, Section 8 entitled "Indemnity and Contribution" and the last paragraph of Section 10 below, the Underwriters will pay all of their costs and expenses, including fees and disbursements of their counsel, stock transfer taxes payable on resale of any of the Shares by them and any advertising expenses connected with any offers they may make.

(j) If the third anniversary of the initial effective date of the Registration Statement occurs before all the Shares have been sold by the Underwriters, prior to the third anniversary to file a new shelf registration statement and to take any other action necessary to permit the public offering of the Shares to continue without interruption; references herein to the Registration Statement shall include the new registration statement declared effective by the Commission;

(k) If requested by the Representatives, to prepare a final term sheet relating to the offering of the Shares, containing only information that describes the final terms of the offering in a form consented to by the Representatives, and to file such final term sheet within the period required by Rule 433(d)(5)(ii) under the Securities Act following the date the final terms have been established for the offering of the Shares.

(l) The Company will promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Shares within the meaning of the Securities Act and (ii) completion of the Restricted Period (as defined in this Section 5(h)).

(m) If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

The Company also covenants with each Underwriter that, without the prior written consent of the Representative identified in Schedule I with the authorization to release this lock-up on behalf of the Underwriters, it will not, during the restricted period set forth in Schedule I hereto (the "**Restricted Period**"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly

or indirectly, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise or (3) file any registration statement with the Commission relating to the offering of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock.

The foregoing sentence shall not apply to (a) the Shares to be sold hereunder, (b) the issuance by the Company of shares of Common Stock upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof of which the Underwriters have been advised in writing, the grant of new options or other equity awards under employee or non-employee director benefit plans existing as of the date hereof and disclosed in the Time of Sale Prospectus, and the filing of one or more registration statements on Form S-8 relating thereto, (c) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, *provided* that (i) such plan does not provide for the transfer of Common Stock during the Restricted Period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Common Stock may be made under such plan during the Restricted Period, or (d) the offer or issuance of up to an aggregate of 5% of shares of Common Stock outstanding in connection with collaboration, intellectual property license or acquisition agreements or arrangements; *provided further*, that in the cases of clauses (b) and (d), that the recipients of such shares agree to be bound by a "lock-up" agreement in the form of Exhibit A hereto and delivers such agreement to the Representative identified in Schedule I prior to such issuance.

7. *Covenants of the Underwriters*. Each Underwriter severally covenants with the Company not to take any action that would result in the Company being required to file with the Commission under Rule 433(d) a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not be required to be filed by the Company thereunder, but for the action of the Underwriter.

8. Indemnity and Contribution. (a) The Company agrees to indemnify and hold harmless each Underwriter, each person, if any, who controls any Underwriter within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act and each affiliate of any Underwriter within the meaning of Rule 405 under the Securities Act from and against any and all losses, claims, damages and liabilities (including, without limitation, any legal or other expenses reasonably incurred in connection with defending or investigating any such action or claim) caused by any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or any amendment thereof, any preliminary prospectus, the Time of Sale Prospectus or any amendment or supplement thereto, any issuer free writing

prospectus as defined in Rule 433(h) under the Securities Act, any Company information that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act, any road show as defined in Rule 433(h) under the Securities Act (a "road show"), or the Prospectus or any amendment or supplement thereto, or any Written Testing the Waters Communication caused by any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, except insofar as such losses, claims, damages or liabilities are caused by any such untrue statement or omission or alleged untrue statement or omission based upon information furnished in writing to the Company by any Underwriter through you expressly for use therein.

(b) Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, its directors, its officers who sign the Registration Statement and each person, if any, who controls the Company within the meaning of either Section 15 of the Securities Act or Section 20 of the Exchange Act to the same extent as the foregoing indemnity from the Company to such Underwriter, but only with reference to information furnished in writing to the Company by any Underwriter through you expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any issuer free writing prospectus, road show or the Prospectus or any amendment or supplement thereto.

(c) In case any proceeding (including any governmental investigation) shall be instituted involving any person in respect of which indemnity may be sought pursuant to Section 8(a) or 8(b), such person (the **"indemnified party**") shall promptly notify the person against whom such indemnity may be sought (the **"indemnifying party**") in writing and the indemnifying party, upon request of the indemnified party, shall retain counsel reasonably satisfactory to the indemnified party to represent the indemnified party and any others the indemnifying party may designate in such proceeding and shall pay the fees and disbursements of such counsel related to such proceeding. In any such proceeding, any indemnified party shall have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel or (ii) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential differing interests between them. It is understood that the indemnifying party shall not, in respect of the legal expenses of any indemnified party in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the fees and expenses of more than one separate firm (in addition to any local counsel) for all such indemnified parties and that all such fees and expenses shall be reimbursed as they are incurred. Such firm shall be designated in writing by the Representative authorized to appoint counsel under this Section 8(b). The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such

consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any loss or liability by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel as contemplated by the second and third sentences of this paragraph, the indemnifying party agrees that it shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 90 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into, and (iii) such indemnifying party shall not have reimbursed the indemnified party, effect any settlement of any pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such proceeding.

(d) To the extent the indemnification provided for in Section 8(a) or 8(b) is unavailable to an indemnified party or insufficient in respect of any losses, claims, damages or liabilities referred to therein, then each indemnifying party under such paragraph, in lieu of indemnifying such indemnified party thereunder, shall contribute to the amount paid or payable by such indemnified party as a result of such losses, claims, damages or liabilities (i) in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other hand from the offering of the Shares or (ii) if the allocation provided by clause 8(d)(i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause 8(d)(i) above but also the relative fault of the Company on the one hand and of the Underwriters on the other hand in connection with the statements or omissions that resulted in such losses, claims, damages or liabilities, as well as any other relevant equitable considerations. The relative benefits received by the Company on the one hand and the Underwriters on the other hand in connection with the statements or omissions received by the Underwriters bear to the aggregate public offering price of the Shares shall be deemed to be in the same respective proportions as the net proceeds from the offering of the Shares (before deducting expenses) received by the Company and the total underwriting discounts and commissions received by the Underwriters on the other hand shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or the omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriters and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission. The Underwriters' respective obligations to contribu

(e) The Company and the Underwriters agree that it would not be just or equitable if contribution pursuant to this Section 8 were determined by *pro rata* allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take account of the equitable considerations referred to in Section 8(d). The amount paid or payable by an indemnified party as a result of the losses, claims, damages and liabilities referred to in Section 8(d) shall be deemed to include, subject to the limitations set forth above, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 8, no Underwriter shall be required to contribute any amount in excess of the amount by which the total price at which the Shares underwritten by it and distributed to the public were offered to the public exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The remedies provided for in this Section 8 are not exclusive and shall not limit any rights or remedies which may otherwise be available to any indemnified party at law or in equity.

(f) The indemnity and contribution provisions contained in this Section 8 and the representations, warranties and other statements of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any termination of this Agreement, (ii) any investigation made by or on behalf of any Underwriter, any person controlling any Underwriter or any affiliate of any Underwriter or by or on behalf of the Company, its officers or directors or any person controlling the Company and (iii) acceptance of and payment for any of the Shares.

9. *Termination*. The Underwriters may terminate this Agreement by notice given by you to the Company, if after the execution and delivery of this Agreement and prior to the Closing Date (i) trading generally shall have been suspended or materially limited on, or by, as the case may be, any of the New York Stock Exchange, the NYSE MKT or the NASDAQ Global Market, (ii) trading of any securities of the Company shall have been suspended on any exchange or in any over-the-counter market, (iii) a material disruption in securities settlement, payment or clearance services in the United States shall have occurred, (iv) any moratorium on commercial banking activities shall have been declared by Federal or New York State authorities or (v) there shall have occurred any outbreak or escalation of hostilities, or any change in financial markets or any calamity or crisis that, in your judgment, is material and adverse and which, singly or together with any other event specified in this clause (v), makes it, in your judgment, impracticable or inadvisable to proceed with the offer, sale or delivery of the Shares on the terms and in the manner contemplated in the Time of Sale Prospectus or the Prospectus.

10. Effectiveness; Defaulting Underwriters. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

If, on the Closing Date or an Option Closing Date, as the case may be, any one or more of the Underwriters shall fail or refuse to purchase Shares that it has or they have agreed to purchase hereunder on such date, and the aggregate number of Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is not more than one-tenth of the aggregate number of the Shares to be purchased on such date, the other Underwriters shall be obligated severally in the proportions that the number of Firm Shares set forth opposite their respective names in Schedule II bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as you may specify, to purchase the Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date; provided that in no event shall the number of Shares that any Underwriter has agreed to purchase pursuant to this Agreement be increased pursuant to this Section 10 by an amount in excess of one-ninth of such number of Shares without the written consent of such Underwriter. If, on the Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Firm Shares and the aggregate number of Firm Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Firm Shares to be purchased on such date, and arrangements satisfactory to you and the Company for the purchase of such Firm Shares are not made within 36 hours after such default, this Agreement shall terminate without liability on the part of any non-defaulting Underwriter or the Company. In any such case either you or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement, in the Time of Sale Prospectus, in the Prospectus or in any other documents or arrangements may be effected. If, on an Option Closing Date, any Underwriter or Underwriters shall fail or refuse to purchase Additional Shares and the aggregate number of Additional Shares with respect to which such default occurs is more than one-tenth of the aggregate number of Additional Shares to be purchased on such Option Closing Date, the non-defaulting Underwriters shall have the option to (i) terminate their obligation hereunder to purchase the Additional Shares to be sold on such Option Closing Date or (ii) purchase not less than the number of Additional Shares that such non-defaulting Underwriters would have been obligated to purchase in the absence of such default. Any action taken under this paragraph shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

If this Agreement shall be terminated by the Underwriters, or any of them, because of any failure or refusal on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement, or if for any reason the Company shall be unable to perform its obligations under this Agreement (which, for the purposes of this Section 10, shall not include termination by the Underwriters pursuant to clauses (i), (iii), (iv) or (v) of Section 9), the Company will reimburse the Underwriters or such Underwriters as have so terminated this Agreement with respect to themselves, severally, for all out-of-pocket expenses (including the fees and disbursements of their counsel) reasonably incurred by such Underwriters in connection with this Agreement or the offering contemplated hereunder.

11. *Information Furnished by the Underwriters*. The statements set forth in the third paragraph concerning the public offering price and concession and reallowances and the tenth paragraph concering stablization by the Underwriters, each appearing under the caption "Underwriting" in the Prospectus, constitute the only information furnished by or on behalf of the Underwriters, as such information is referred to in Sections 1 and 8 hereof.

12. *Entire Agreement*. (a) This Agreement, together with any contemporaneous written agreements and any prior written agreements (to the extent not superseded by this Agreement) that relate to the offering of the Shares, represents the entire agreement between the Company and the Underwriters with respect to the preparation of any preliminary prospectus, the Time of Sale Prospectus, the Prospectus, the conduct of the offering, and the purchase and sale of the Shares.

(b) The Company acknowledges that in connection with the offering of the Shares: (i) the Underwriters have acted at arms length, are not agents of, and owe no fiduciary duties to, the Company or any other person, (ii) the Underwriters owe the Company only those duties and obligations set forth in this Agreement and prior written agreements (to the extent not superseded by this Agreement), if any, and (iii) the Underwriters may have interests that differ from those of the Company. The Company waives to the full extent permitted by applicable law any claims it may have against the Underwriters arising from an alleged breach of fiduciary duty in connection with the offering of the Shares.

13. *Counterparts*. This Agreement may be signed in two or more counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

14. Applicable Law. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York.

15. *Headings*. The headings of the sections of this Agreement have been inserted for convenience of reference only and shall not be deemed a part of this Agreement.

16. *Notices*. All communications hereunder shall be in writing and effective only upon receipt and (a) if to the Underwriters shall be delivered, mailed or sent to you at the address set forth in Schedule I hereto; and (b) if to the Company shall be delivered, mailed or sent to the address set forth in Schedule I hereto.

[The Remainder of This Page Intentionally Left Blank; Signature Page Follows]

²⁴

Very truly yours,

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler

Name: John P. Butler Title: President & Chief Executive Officer

[Signature Page to Underwriting Agreement]

Accepted as of the date hereof

Morgan Stanley & Co. LLC UBS Securities LLC

Acting on behalf of themselves and the several Underwriters named in Schedule II hereto

By: Morgan Stanley & Co. LLC

By: <u>/s/ Albert Hwang</u> Name: Albert Hwang Title: Managing Director

By: UBS Securities LLC

By:

Name: Title:

By:

Name: Title:

[Signature Page to Underwriting Agreement]

Accepted as of the date hereof

Morgan Stanley & Co. LLC UBS Securities LLC

Acting on behalf of themselves and the several Underwriters named in Schedule II hereto

By: Morgan Stanley & Co. LLC

By:

Name: Title:

By: UBS Securities LLC

By: /s/ Lee Schechter Name: Lee Schechter Title: Director

By: /s/ Ridwan Obaray

Name: Ridwan Obaray Title: Executive Director

[Signature Page to Underwriting Agreement]

Representatives:				
Representatives authorized to release lock-up under Section 6:		Morgan Stanley & Co. LLC UBS Securities LLC		
Representatives authorized to appoint counsel under Section 8(c):		Morgan Stanley & Co. LLC		
		UBS Securities LLC		
Registration Statement File No.:		333-203206		
Time of Sale Prospectus		Prospectus dated April 14, 2015 relating to the Shelf Securities		
		The preliminary prospectus supplement dated January 4, 2016 relating to the Shares		
		The free writing prospectus dated January 6, 2016 relating to the Shares		
	4.	Firm Shares: 7,250,000 Additional Shares: 1,087,500 Price per share to the public: \$9.00		
Lock-up Restricted Period:		90 days		
Title of Shares to be purchased:		Common Stock of Akebia Therapeutics, Inc., par value \$0.00001 per share		
Number of Firm Shares:		7,250,000 shares		
Number of Additional Shares		1,087,500 shares		
Purchase Price:		\$8.460 a share		
Initial Public Offering Price		\$9.000 a share		
Selling Concession:		\$0.324 a share		
Reallowance:		n/a		
Closing Date and Time:		January 12, 2016 10:00 a.m.		

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Address for Notices to Underwriters:

Address for Notices to the Company:

Latham & Watkins LLP John Hancock Tower 200 Clarendon Street Boston, MA 02116

Morgan Stanley & Co. LLC 1585 Broadway Avenue New York, New York 10036 Attention: Equity Syndicate Desk

UBS Securities LLC 1285 Avenue of the Americas New York, New York 10019 Attention: Syndicate

245 First Street, Suite 1100 Cambridge, Massachusetts 02142

I-2

Schedule II

Underwriter	Number of Firm Shares To Be Purchased
Morgan Stanley & Co. LLC	2,646,250
UBS Securities LLC	2,646,250
JMP Securities LLC	870,000
Needham & Company LLC	725,000
Brean Capital, LLC	362,500
Total:	7.250.000

Written Testing the Waters Communications

None.

III-1

Persons Delivering Lock-up Agreements

Directors:

Michael Clayman Anupam Dalal Maxine Gowen Duane Nash Ronald Renaud Muneer Satter Michael Wyzga

Officers:

John Butler Jason Amello Bradley Maroni Nicole Hadas Michel Dahan

Securityholders:

Trusts and Other Entities Affiliated with Muneer A. Satter Kearny Venture Partners Kearney Venture Partners, L.P. Kearney Venture Partners Entrepreneurs Fund, L.P. Thomas Weisel Healthcare Venture Partners, L.P.

IV-1

[FORM OF LOCK-UP LETTER]

Morgan Stanley & Co. LLC UBS Securities LLC Together with the other Underwriters Named in Schedule II to the Underwriting Agreement referred to herein

c/o Morgan Stanley & Co. LLC 1585 Broadway New York, NY 10036

> UBS Securities LLC 299 Park Avenue New York, New York 10171-0026

Ladies and Gentlemen:

The understands that Morgan Stanley & Co. LLC and UBS Securities LLC (together, the "**Representatives**") propose to enter into an Underwriting Agreement (the "**Underwriting Agreement**") with Akebia Therapeutics, Inc., a Delaware corporation (together with any successor, the "**Company**"), providing for the public offering (the "**Public Offering**") by the several Underwriters, including the Representatives (the "**Underwriters**"), of shares (the "**Shares**") of the Common Stock, par value \$0.00001 per share, of the Company (the "**Common Stock**").

To induce the Underwriters that may participate in the Public Offering to continue their efforts in connection with the Public Offering, the undersigned hereby agrees that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, during the period commencing on the date hereof and ending 60 days after the date of the final prospectus (the "**Restricted Period**") relating to the Public Offering (the "**Prospectus**"), (1) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of Common Stock beneficially owned (as such term is used in Rule 13d-3 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")), by the undersigned or any other securities so owned convertible into or exercisable or exchangeable for Common Stock or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise. The foregoing sentence shall not apply to (a) transactions relating to shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock or any security convertible into or exercisable or common Stock or any security convertible into or exercisable or exchangeable for Common Stock or any security convertible into or exercisable or otherwise. The foregoing sentence shall not apply to (a) transactions relating to shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock as a bona fide gift; (c) transfers of shares of Common Stock or any security convertible into or

exercisable or exchangeable for Common Stock by will or intestacy; (d) the exercise of options to purchase shares of Common Stock granted under a stock incentive plan or stock purchase plan of the Company existing as of the date hereof and described in the Prospectus and any related transfer of Common Stock to the Company (i) deemed to occur upon the cashless exercise of such options or (ii) for the purpose of paying the exercise price of such options or for paying taxes (including estimated taxes) due as a result of the exercise of such options or as a result of the vesting of such shares of Common Stock under such restricted stock awards, provided that any shares of Common Stock issued pursuant to such exercise shall be subject to the restrictions set forth herein; (e) transfers to the Company for the purpose of satisfying tax withholding obligations upon the vesting of other equity incentive awards granted under a stock incentive plan or stock purchase plan of the Company existing as of the date hereof and described in the Prospectus; (f) transfers or distributions not involving a disposition for value of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock to limited or general partners, stockholders or members of the undersigned, or if the undersigned is a corporation, to a wholly-owned subsidiary of the undersigned; (g) transfers of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock made by the undersigned to (1) any trust, corporation, partnership, limited liability company or other legal entity who, directly or indirectly, controls, is controlled by, or is under common control with the undersigned, (2) any trust or other legal entity for which the undersigned or the undersigned's spouse serves as trustee or investment advisor, or (3) any member of the immediate family of the undersigned or any trust or other legal entity for the direct or indirect benefit of the undersigned or any member of the immediate family of the undersigned; (h) transfers of shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock pursuant to a sale of, or an offer to purchase, 100% of the outstanding shares of Common Stock, whether pursuant to a merger, tender offer or otherwise, to a third party or group of third parties, provided that in the event that such merger, tender offer or other transaction is not completed, the Common Stock and any security convertible into or exercisable or exchangeable for Common Stock shall remain subject to the restrictions set forth herein; or (i) the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of Common Stock, provided that (1) such plan does not provide for the transfer of Common Stock during the Restricted Period and (2) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the Company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of Common Stock may be made under such plan during the Restricted Period, provided, however, that in the case of (1) any transfer or distribution pursuant to clause (b), (c), (f) or (g), each donee, distributee or transferee shall sign and deliver a lock-up letter substantially in the form of this letter and (2) any transaction, transfer, exercise or distribution pursuant to clause (a), (b), (c), (e), (f), or (g), no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of Common Stock, shall be required or shall be voluntarily made during the Restricted Period (other than a filing on Form 5 made after the expiration of the Restricted Period). In addition, the undersigned agrees that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, during the Restricted Period, make any demand for or exercise any right with respect to, the registration of any shares of Common Stock or any

security convertible into or exercisable or exchangeable for Common Stock; *provided that* the undersigned may make a demand under any registration rights agreement with the Company existing as of the date hereof and described in the Prospectus for, and exercise its rights under any such registration rights agreement with respect to, the registration after the expiration of the Restricted Period of shares of Common Stock that does not require the filing of a registration statement or any public announcement or activity regarding the registration during Restricted Period (and no such public announcement or activity shall be voluntarily made or taken during the Restricted Period). The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the undersigned's shares of Common Stock except in compliance with the foregoing restrictions.

The undersigned understands that the Company and the Underwriters are relying upon this agreement in proceeding toward consummation of the Public Offering. The undersigned further understands that this agreement is irrevocable and shall be binding upon the undersigned's heirs, legal representatives, successors and assigns.

This agreement (and for the avoidance of doubt, the Restricted Period described herein) and related restrictions shall automatically terminate upon the earliest to occur, if any, of (i) the Representatives, on behalf of the Underwriters, on the one hand, or the Company, on the other hand, advising the other in writing prior to the execution of the Underwriting Agreement that they have or it has determined not to proceed with the Public Offering, (ii) the termination of the Underwriting Agreement before the sale of any Shares to the Underwriters, (iii) the registration statement filed with the SEC with respect to the Public Offering is withdrawn or (iv) February 29, 2016, in the event the closing of the Public Offering shall not have occurred on or before such date.

Whether or not the Public Offering actually occurs depends on a number of factors, including market conditions. Any Public Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and the Underwriters.

Very truly yours,

(Print Name)

(Signature)

(Address)



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

January 12, 2016

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

Re: Registration Statement on Form S-3 (Registration No. 333-203206)

Ladies and Gentlemen:

We have acted as counsel to Akebia Therapeutics, Inc., a Delaware corporation (the "<u>Company</u>") in connection with the issuance and sale by the Company of 8,337,500 shares (the "<u>Shares</u>") of its common stock, \$0.00001 par value per share (the "<u>Shares</u>"), including the additional 1,087,500 shares the underwriters have the option to purchase pursuant to the Underwriting Agreement (as defined below), pursuant to the above-referenced registration statement (as amended through the date hereof (the "<u>Registration Statement</u>"), filed by the Company with the Securities and Exchange Commission (the "<u>Commission</u>") under the Securities Act of 1933, as amended (the "<u>Securities Act</u>"). The Shares are being sold pursuant to an underwriting agreement, dated January 6, 2015, by and among the Company and the underwriters named therein (the "<u>Underwriting Agreement</u>").

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 General Corporation Law of the State of Delaware.

Based upon and subject to the foregoing, and subject to the qualifications, assumptions and limitations stated herein, we are of the opinion that the Shares, when issued and delivered in accordance with the terms of the Underwriting Agreement against payment of the consideration set forth therein, will be duly authorized, validly issued, fully paid and non-assessable.

ROPES & GRAY LLP

Akebia Therapeutics, Inc.

We hereby consent to your filing this opinion as an exhibit to a Current Report on Form 8-K that is incorporated by reference in the Registration Statement and to the use of our name therein and in the related Prospectus Supplement 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