# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 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): October 17, 2018

# Aclaris Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) **001-37581** (Commission File Number) **46-0571712** (IRS Employer Identification No.)

640 Lee Road, Suite 200 Wayne, PA 19087

(Address of principal executive offices, including zip code)

(484) 324-7933

(Registrant's telephone number, including area code)

N/A

(Former name or former address, if changed since last report)

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:

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

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

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

## Item 1.01 Entry into a Material Definitive Agreement.

On October 17, 2018, Aclaris Therapeutics, Inc. (the "*Company*") entered into an underwriting agreement (the "*Underwriting Agreement*") with Leerink Partners LLC and Evercore Group L.L.C., as representatives of the underwriters (the "*Underwriters*"), to issue and sell 8,645,000 shares of common stock of the Company, par value \$0.00001 per share ("*Common Stock*"), in an underwritten public offering pursuant to effective registration statements on Form S-3 (File Nos. 333-214384 and 333-227880) and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission (the "*Offering*"). The offering price to the public is \$10.75 per share of Common Stock, and the Underwriters have agreed to purchase the shares from the Company pursuant to the Underwriting Agreement at a price of \$10.105 per share. In addition, the Company granted the Underwriters an option to purchase, for a period of 30 days, up to an additional 1,296,750 shares of Common Stock. The Company estimates that the net proceeds from the Offering will be approximately \$87.1 million, or approximately \$100.2 million if the Underwriters exercise in full their option to purchase additional shares of Common Stock, in each case after deducting underwriting discounts and commissions and estimated offering expenses. The closing of the Offering is expected to occur on October 22, 2018, subject to customary closing conditions.

The Underwriting Agreement contains customary representations, warranties, covenants and agreements by the Company, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended (the "*Securities Act*"), other obligations of the parties and termination provisions. The representations, warranties and covenants contained in the Underwriting Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties. A copy of the Underwriting Agreement is filed as Exhibit 1.1 to this Current Report on Form 8-K and is incorporated herein by reference. The foregoing description of the Underwriting Agreement is qualified in its entirety by reference to such exhibit. A copy of the opinion of Cooley LLP as to the legality of the shares of Common Stock to be issued and sold in the Offering and related consent is filed as Exhibit 5.1 to this Current Report on Form 8-K.

## Item 8.01 Other Events.

On October 17, 2018, the Company issued a press release announcing the commencement of the Offering and an additional press release announcing that it had priced the Offering. Copies of the press releases are filed herewith as Exhibits 99.1 and 99.2, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

On October 17, 2018, the Company filed with the Securities and Exchange Commission a preliminary prospectus supplement pursuant to Rule 424(b)(5) under the Securities Act (the "*Preliminary Prospectus Supplement*"), in connection with the Offering. The Preliminary Prospectus Supplement contains updated disclosure of certain of the Company's risk factors, as well as a supplemental description of certain aspects of the Company's business, including its intellectual property. Accordingly, the Company is filing information with this Current Report on Form 8-K for the purpose of supplementing and updating certain risk factor and intellectual property disclosures contained in the Company's prior public filings, including those discussed under the heading "Item 1A. Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, filed with the Securities and Exchange Commission on March 12, 2018. The updated disclosures are filed as Exhibit 99.3 to this Current Report on Form 8-K and are incorporated herein by reference.

## **Caution Concerning Forward-Looking Statements**

This Current Report on Form 8-K may contain forward-looking statements made in reliance upon the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include all statements that do not relate solely to historical or current facts, and can be identified by the use of words such as "may," "will," "expect," "project," "estimate," "anticipate," "plan," "believe," "potential," "should," "continue" or the negative versions of those words or other comparable words. These forward-looking statements include statements about the Company's public offering, such as expected net proceeds and anticipated closing date. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all. The Company's forward-looking statements also involve assumptions that, if they prove incorrect, would cause its results to differ materially from those expressed or implied by such forward-looking statements. These and other risks concerning the Company's business are described in additional detail in the Company's Annual Report on Form 10-K for the year ended December 31, 2017, the Preliminary Prospectus Supplement and in the Company's

other Periodic and Current Reports filed with the Securities and Exchange Commission. The Company is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

## Item 9.01 Financial Statements and Exhibits.

## (d) Exhibits

Exhibit Number	Exhibit Description
1.1	<u>Underwriting Agreement by and among Aclaris Therapeutics, Inc., Leerink Partners LLC and Evercore Group L.L.C.,</u> <u>dated October 17, 2018.</u>
5.1	<u>Opinion of Cooley LLP.</u>
23.1	Consent of Cooley LLP (included in Exhibit 5.1).
99.1	Press Release, titled "Aclaris Announces Proposed Public Offering of Common Stock," dated October 17, 2018.
99.2	Press Release, titled "Aclaris Announces Pricing of Public Offering of Common Stock," dated October 17, 2018.
99.3	Updated Company Disclosure.

## SIGNATURES

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.

## ACLARIS THERAPEUTICS, INC.

By: /s/ Frank Ruffo

Frank Ruffo Chief Financial Officer

Date: October 18, 2018

## 8,645,000 Aclaris Therapeutics, Inc. Common Shares <u>UNDERWRITING AGREEMENT</u>

October 17, 2018

LEERINK PARTNERS LLC EVERCORE GROUP L.L.C. As Representatives of the several Underwriters

c/o LEERINK PARTNERS LLC One Federal Street, 37<sup>th</sup> Floor Boston, Massachusetts 02110

c/o EVERCORE GROUP L.L.C. 55 East 52<sup>nd</sup> Street New York, New York 10055

Ladies and Gentlemen:

**Introductory.** Aclaris Therapeutics, Inc., a Delaware corporation (the "**Company**"), proposes to issue and sell to the several underwriters named in <u>Schedule A</u> (the "**Underwriters**") an aggregate of 9,941,750 shares of its common stock, par value \$0.00001 per share (the "**Shares**"). The 8,645,000 Shares to be sold by the Company are called the "**Firm Shares**." In addition, the Company has granted to the Underwriters an option to purchase up to an additional 1,296,750 Shares as provided in Section 2. The additional 1,296,750 Shares to be sold by the Company pursuant to such option are collectively called the "**Optional Shares**." The Firm Shares and, if and to the extent such option is exercised, the Optional Shares are collectively called the "**Offered Shares**." Leerink Partners LLC ("**Leerink**") and Evercore Group L.L.C. ("**Evercore**") have agreed to act as representatives of the several Underwriters (in such capacity, the "**Representatives**") in connection with the offering and sale of the Offered Shares. To the extent there are no additional underwriters listed on <u>Schedule A</u>, the term "Representatives" as used herein shall mean you, as Underwriters, and the term "Underwriters" shall mean either the singular or the plural, as the context requires.

The Company has prepared and filed with the Securities and Exchange Commission (the "**Commission**") a shelf registration statement on Form S-3, File No. 333-214384, including a base prospectus (the "**Base Prospectus**") to be used in connection with the public offering and sale of the Offered Shares. Such registration statement, as amended, including the financial statements, exhibits and schedules thereto, in the form in which it became effective under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (collectively, the "**Securities Act**"), including all documents incorporated or deemed to be incorporated by reference therein and any information deemed to be a part thereof at the time of effectiveness pursuant to Rule 430A or 430B under the Securities Act, is called the "**Registration Statement**." Any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offer and sale of the Offered Shares is called the "**Rule 462(b) Registration Statement**," and from and after the date and time of filing of any such Rule 462(b) Registration Statement the term "Registration Statement" shall include the Rule 462(b) Registration Statement. The preliminary prospectus supplement dated October 17, 2018 describing the Offered Shares and the offering thereof (the "**Preliminary Prospectus Supplement**"), together with the Base Prospectus, is called the "**Preliminary Prospectus**," and the Preliminary Prospectus and any other prospectus

supplement to the Base Prospectus in preliminary form that describes the Offered Shares and the offering thereof and is used prior to the filing of the Prospectus (as defined below), together with the Base Prospectus, is called a "preliminary prospectus." As used herein, the term "Prospectus" shall mean the final prospectus supplement to the Base Prospectus that describes the Offered Shares and the offering thereof (the "Final Prospectus Supplement"), together with the Base Prospectus, in the form first used by the Underwriters to confirm sales of the Offered 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. References herein to the Preliminary Prospectus, any preliminary prospectus and the Prospectus shall refer to both the prospectus supplement and the Base Prospectus components of such prospectus. As used herein, "Applicable Time" is 6:15 p.m. (New York City time) on October 17, 2018. As used herein, "free writing prospectus" has the meaning set forth in Rule 405 under the Securities Act, and "Time of Sale Prospectus" means the Preliminary Prospectus, as amended or supplemented immediately prior to the Applicable Time, together with the free writing prospectuses, if any, identified in <u>Schedule B</u> hereto and the pricing information identified in <u>Schedule</u> <u>C</u> hereto. As used herein, "Road Show" means a "road show" (as defined in Rule 433 under the Securities Act) relating to the offering of the Offered Shares contemplated hereby that is a "written communication" (as defined in Rule 405 under the Securities Act). As used herein, "Section 5(d) Written Communication" means each written communication (within the meaning of Rule 405 under the Securities Act) that is made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company to one or more potential investors that are qualified institutional buyers ("QIBs") and/or institutions that are accredited investors ("IAIs"), as such terms are respectively defined in Rule 144A and Rule 501(a) under the Securities Act, to determine whether such investors might have an interest in the offering of the Offered Shares; "Section 5(d) Oral Communication" means each oral communication, if any, made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company made to one or more QIBs and/or one or more IAIs to determine whether such investors might have an interest in the offering of the Offered Shares; "Marketing Materials" means any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Offered Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically); and "Permitted Section 5(d) Communication" means the Section 5(d) Written Communication(s) and Marketing Materials listed on Schedule D attached hereto.

All references in this Agreement to the Registration Statement, the Preliminary Prospectus, any preliminary prospectus, the Base Prospectus and the Prospectus shall include the documents incorporated or deemed to be incorporated by reference therein. All references in this Agreement to financial statements and schedules and other information which are "contained," "included" or "stated" in, or "part of" the Registration Statement, the Rule 462(b) Registration Statement, the Preliminary Prospectus, any preliminary prospectus, the Base Prospectus, the Time of Sale Prospectus or the Prospectus, and all other references of like import, shall be deemed to mean and include all such financial statements and schedules and other information which is or is deemed to be incorporated by reference in the Registration Statement, the Rule 462(b) Registration Statement, the Preliminary Prospectus, any preliminary prospectus, as the case may be. All references in this Agreement to amendments or supplements to the Registration Statement, the Preliminary Prospectus, any document under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the "**Exchange Act**") that is or is deemed to be incorporated by references in this Agreement to (i) the Registration Statement, the Preliminary Prospectus, any preliminary prospectus, as the case may be. All references in this Agreement to (i) the Registration Statement, the Preliminary Prospectus, any preliminary prospectus, as the case may be. All references in this Agreement to (i) the Registration Statement, the Preliminary Prospectus, any preliminary prospectus, as the case may be. All references in this Agreement to its Electronic Data Gathering, Analysis and Retrieval System ("**EDGAR**") and (ii) the Prospectus shall be deemed to

include any "electronic Prospectus" provided for use in connection with the offering of the Offered Shares as contemplated by Section 3(n) of this Agreement. In the event that the Company has only one subsidiary, then all references herein to "subsidiaries" of the Company shall be deemed to refer to such single subsidiary, <u>mutatis mutandis</u>.

The Company hereby confirms its agreements with the Underwriters as follows:

Section 1. Representations and Warranties of the Company. The Company hereby represents, warrants and covenants to each Underwriter, as of the date of this Agreement, as of the First Closing Date (as hereinafter defined) and as of each Option Closing Date (as hereinafter defined), if any, as follows:

(a) *Compliance with Registration Requirements.* The Registration Statement has become effective under the Securities Act. The Company has complied, to the Commission's satisfaction with all requests of the Commission for additional or supplemental information, if any. No stop order suspending the effectiveness of the Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are contemplated or threatened by the Commission. At the time the Company's Annual Report on Form 10-K for the year ended December 31, 2017 (the "Annual Report") was filed with the Commission, or, if later, at the time the Registration Statement was originally filed with the Commission, the Company met the then-applicable requirements for use of Form S-3 under the Securities Act. The documents incorporated or deemed to be incorporated by reference in the Registration Statement, the Time of Sale Prospectus and the Prospectus, at the time they were or hereafter are filed with the Commission, or became effective under the Exchange Act, as the case may be, complied and will comply in all material respects with the requirements of the Exchange Act.

Disclosure. Each preliminary prospectus and the Prospectus when filed complied in all material respects with the Securities Act and, if (b) filed by electronic transmission pursuant to EDGAR, was identical (except as may be permitted by Regulation S-T under the Securities Act) to the copy thereof delivered to the Underwriters for use in connection with the offer and sale of the Offered Shares. Each of the Registration Statement and any posteffective amendment thereto, at the time it became or becomes effective, complied and will comply in all material respects with the Securities Act and did not and 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. As of the Applicable Time, the Time of Sale Prospectus did not, and at the First Closing Date (as defined in Section 2) and at each applicable Option Closing Date (as defined in Section 2), 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. The Prospectus, as of its date, did not, and at the First Closing Date and at each applicable Option Closing Date, will not, contain any untrue statement of a material fact or 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. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement or any posteffective amendment thereto, or the Prospectus or the Time of Sale Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with written information relating to any Underwriter furnished to the Company in writing by the Representatives expressly for use therein, it being understood and agreed that the only such information consists of the information described in Section 9(b) below. There are no contracts or other documents required to be described in the Time of Sale Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which have not been described or filed as required.

(c) *Free Writing Prospectuses; Road Show.* As of the determination date referenced in Rule 164(h) under the Securities Act, the Company was not, is not or will not be (as applicable) an "ineligible



issuer" in connection with the offering of the Offered Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Each 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. 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 on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act, including timely filing with the Commission or retention where required and legending, and each such free writing prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Offered Shares did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Prospectus or any preliminary prospectus and not superseded or modified. Except for the free writing prospectuses, if any, identified in <u>Schedule B</u>, and electronic road shows, if any, furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior written consent, prepare, use or refer to, any free writing prospectus. Each Road Show, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, 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.

(d) Distribution of Offering Material By the Company. Prior to the later of (i) the expiration or termination of the option granted to the several Underwriters in Section 2 and (ii) the completion of the Underwriters' distribution of the Offered Shares, the Company has not distributed and will not distribute any offering material in connection with the offering and sale of the Offered Shares other than the Registration Statement, the Time of Sale Prospectus, the Prospectus or any free writing prospectus reviewed and consented to by the Representatives, the free writing prospectuses, if any, identified on <u>Schedule B</u> hereto and any Permitted Section 5(d) Communications.

(e) *The Underwriting Agreement.* This Agreement has been duly authorized, executed and delivered by the Company.

(f) Authorization of the Offered Shares. The Offered Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Offered Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Offered Shares.

(g) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(h) No Material Adverse Change. Except as otherwise disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement, the Time of Sale Prospectus and the Prospectus: (i) there has been no material adverse change, or any development that would reasonably be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change being referred to herein as a "Material Adverse Change"); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike,

labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and its subsidiaries, considered as one entity, or has entered into any transactions not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company or its subsidiaries and there has been no dividend or distribution of any kind declared, paid or made by the Company or any repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(i) Independent Accountants. PricewaterhouseCoopers LLP, which has expressed its opinion with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus, is (i) an independent registered public accounting firm as required by the Securities Act, the Exchange Act, and the rules of the Public Company Accounting Oversight Board ("PCAOB"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(j) Financial Statements. The financial statements filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus present fairly, in all material respects, the financial position of the Company as of the dates indicated and the results of their operations, changes in stockholders' equity and cash flows for the periods specified. Such financial statements have been prepared in conformity with generally accepted accounting principles applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto and except in the case of unaudited financial statements, which are subject to normal and recurring year end adjustments and do not contain certain footnotes as permitted by the applicable rules of the Commission. The interactive data in eXtensible Business Reporting Language included 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. No other financial data set forth in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Selected Consolidated Financial Data" fairly present, in all material respects, the information set forth therein on a basis consistent with that of the audited financial statements contained in the Registration Statement, the Time of Sale Prospectus. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(k) Company's Accounting System. The Company makes and keeps accurate books and records and maintains a system of internal accounting controls designed, and which the Company believes is sufficient, to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain accountability for assets; (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 existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(I) Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting. The Company has established and maintains disclosure controls and

procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities. Since the end of the Company's most recent audited fiscal year, there have been no significant deficiencies or material weakness in the Company's internal control over financial reporting (whether or not remediated) and 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. The Company is not aware of any change in its internal controls over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to material control over financial reporting that has occurred during its most recent fiscal quarter that has materially affected, or is reasonably likely to material control over financial reporting.

(m) Incorporation and Good Standing of the Company. The Company has been duly incorporated and is validly existing as a corporation in good standing under the laws of the jurisdiction of its incorporation and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business and is in good standing in the Commonwealth of Pennsylvania and each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or be in good standing would not reasonably be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or otherwise), earnings, business, properties, operations, assets, liabilities or prospects of the Company and its subsidiaries (a "Material Adverse Effect").

(n) Subsidiaries. Each of the Company's "subsidiaries" (for purposes of this Agreement, as defined in Rule 405 under the Securities Act) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation, partnership or limited liability company, as applicable, in good standing under the laws of the jurisdiction of its incorporation or organization and has the power and authority (corporate or other) to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus. Each of the Company's subsidiaries is duly qualified as a foreign corporation, partnership or limited liability company, as applicable, to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or be in good standing would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. All of the issued and outstanding capital stock or other equity or ownership interests of each of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are, except as disclosed in the Registration Statement, the Time of Sale Prospectus or the Prospectus, owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the Registration Statement and Aclaris Life Sciences, Inc. and Confluence Discovery Technologies, Inc.

(o) Capitalization and Other Capital Stock Matters. The authorized, issued and outstanding capital stock of the Company is as set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Description of Capital Stock" (other than for subsequent issuances, if any, pursuant to employee benefit plans, or upon the exercise of outstanding options or warrants, in each case as described in the Registration Statement, the Time of Sale Prospectus. The Shares (including the Offered Shares) conform in all material respects to the description thereof contained in the Time of Sale Prospectus. All of the issued and outstanding Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all federal and state securities laws. None of the outstanding Shares was issued in violation of any preemptive rights,

rights of first refusal or other similar rights to subscribe for or purchase securities of the Company that have not been duly waived or satisfied. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those described in the Registration Statement, the Time of Sale Prospectus and the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus accurately and fairly presents in all material respects the information required to be shown with respect to such plans, arrangements, options and rights.

(p) Stock Exchange Listing. The Shares are registered pursuant to Section 12(b) or 12(g) of the Exchange Act and are listed on The Nasdaq Global Select Market (the "Nasdaq"), subject only to official notice of issuance and the Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Shares under the Exchange Act or delisting the Shares from Nasdaq, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing. To the Company's knowledge, it is in compliance with all applicable listing requirements of Nasdaq.

Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required. Neither the Company nor any of its (q) subsidiaries is in violation of its charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("Default") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of their respective properties or assets are subject (each, an "Existing Instrument"), except for such Defaults as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The Company's execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus and the issuance and sale of the Offered Shares (including the use of proceeds from the sale of the Offered Shares as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Use of Proceeds") (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the charter or by-laws, partnership agreement or operating agreement or similar organizational documents, as applicable, of the Company or any subsidiary (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument, except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries, except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws or the Financial Industry Regulatory Authority, Inc. ("FINRA"). As used herein, a "Debt Repayment Triggering Event" means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the

repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(r) *Compliance with Laws.* The Company and its subsidiaries have been and are in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(s) No Material Actions or Proceedings. There is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not reasonably be expected to have a Material Adverse Effect. No material labor dispute with the employees of the Company or any of its subsidiaries, or with the employees of any principal supplier, manufacturer, customer or contractor of the Company, exists or, to the knowledge of the Company, is threatened or imminent.

Intellectual Property Rights. The Company and its subsidiaries own, or have obtained valid and enforceable licenses for, the inventions, (t) patent applications, patents, trademarks, trade names, service names, copyrights, trade secrets and other intellectual property described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as being owned or licensed by them or, except as disclosed in the Registration Statement, the Time of Sale Prospectus or the Prospectus, which are necessary for the conduct of their respective businesses as currently conducted or as currently proposed to be conducted (collectively, "Intellectual Property"), and there are no unreleased liens or security interests which have been filed against any of the patents owned by the Company or any of its subsidiaries. To the Company's knowledge, and except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect; (i) there are no third parties who have rights to any Intellectual Property, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus as licensed to the Company or one or more of its subsidiaries; and (ii) except as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, there is no infringement, misappropriation or violation by third parties of any Intellectual Property. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company's rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property (except standard patent examination proceedings before the applicable governmental authorities), and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company or any of its subsidiaries infringes or otherwise violates, or would, upon the commercialization of any product or service described in the Registration Statement, the Time of Sale Prospectus or the Prospectus as under development, infringe or violate, any patent, trademark, trade name, service name, copyright, trade secret or other proprietary rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, the Company and its subsidiaries have complied with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or any subsidiary, and all such agreements are in full force and effect. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse

Effect, the drug candidates described in the Registration Statement, the Time of Sale Prospectus and the Prospectus as under development by the Company or any subsidiary fall within the scope of the claims of one or more patents or applications relating to the drug candidate or its intended use owned by, or exclusively licensed to, the Company or any subsidiary.

To the Company's knowledge, no employee of the Company is in or has ever been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company or actions undertaken by the employee while employed with the Company.

The Company has disclosed to the U.S. Patent and Trademark Office all information relevant to the patentability of its inventions in accordance with 37 C.F.R. Section 1.56, and has not made any misrepresentation or concealed any information from the USPTO in any of the patents or patent applications owned or licensed to the Company, or in connection with the prosecution thereof, in violation of 37 C.F.R. Section 1.56.

(u) All Necessary Permits, etc. The Company and its subsidiaries possess such valid and current certificates, authorizations or permits required by state, federal or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted ("Permits"), except where failure to so possess would not reasonably be expected to, individually or in the aggregate, result in a Material Adverse Effect. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect, neither the Company nor any of its subsidiaries is in violation of, or in default under, any of the Permits or has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such Permit.

(v) *Title to Properties.* The Company and its subsidiaries have good and marketable title to all of the real and personal property and other assets reflected as owned in the financial statements referred to in Section 1(j) above (or elsewhere in the Registration Statement, the Time of Sale Prospectus or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except such as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. The real property, improvements, equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or such subsidiary.

(w) Tax Law Compliance. The Company and its subsidiaries have filed all necessary federal, state and foreign income and franchise tax returns or have properly requested extensions thereof and have paid all taxes required to be paid by any of them and, if due and payable, any related or similar assessment, fine or penalty levied against any of them except as may be being contested in good faith and by appropriate proceedings. The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 1(j) above in respect of all federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company or any of its subsidiaries is being contested or has not otherwise been finally determined.

(x) *Insurance.* Each of the Company and its subsidiaries is insured by financially sound and reputable institutions with policies in such amounts and with such deductibles and covering such risks as are generally deemed adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction and acts of vandalism and policies covering the Company and its subsidiaries for

product liability claims and clinical trial liability claims. The Company has no reason to believe that it or any of its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(y) Compliance with Environmental Laws. Except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect: (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "Hazardous Materials") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "Environmental Laws and are each in compliance with their requirements; (iii) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its subsidiaries; and (iv) to the Company's knowledge, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(z) ERISA Compliance. The Company and its subsidiaries and any "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "ERISA")) established or maintained by the Company, its subsidiaries or their "ERISA Affiliates" (as defined below), are in compliance in all material respects with ERISA. "ERISA Affiliate" means, with respect to the Company or any of its subsidiaries, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "Code") of which the Company or such subsidiary is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates. No "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates. No "employee benefit plan" established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates. No "employee benefit plan" established or unfunded benefit liabilities" (as defined under ERISA). Neither the Company, its subsidiaries nor any of their ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each employee benefit plan established or maintained by the Company, its subsidiaries or any of their ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification.

(aa) *Company Not an "Investment Company.*" The Company is not, and will not be, either after receipt of payment for the Offered Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus or the

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Prospectus, required to register as an "investment company" under the Investment Company Act of 1940, as amended (the "Investment Company Act").

(bb) *No Price Stabilization or Manipulation; Compliance with Regulation M.* Neither the Company nor any of its subsidiaries has taken, directly or indirectly, any action designed to or that would reasonably be expected to cause or result in stabilization or manipulation of the price of the Shares or of any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act (**"Regulation M"**)) with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(cc) *Related-Party Transactions.* There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus that have not been described as required.

(dd) *FINRA Matters*. All of the information provided to the Underwriters or to counsel for the Underwriters by the Company, its counsel, its officers and directors and, to the Company's knowledge, the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Offered Shares is true, complete, correct in all material respects and compliant with FINRA's rules and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct in all material respects.

(e) Parties to Lock-Up Agreements. The Company has furnished to the Underwriters a letter agreement in the form attached hereto as <u>Exhibit A</u> (the "Lock-up Agreement") from each of the persons listed on <u>Exhibit B</u>. Such <u>Exhibit B</u> lists under an appropriate caption the directors and officers of the Company and certain of its security holders. If any additional persons shall become directors or officers of the Company prior to the end of the Company Lock-up Period (as defined below), the Company shall cause each such person, prior to or contemporaneously with their appointment or election as a director or officer of the Company, to execute and deliver to the Representatives a Lock-up Agreement.

(ff) Statistical and Market-Related Data. All statistical, demographic and market-related data included in the Registration Statement, the Time of Sale Prospectus or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate in all material respects. To the extent required, the Company has obtained the written consent to the use of such data from such sources.

(gg) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any employee or agent of the Company or any subsidiary, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law or of the character required to be disclosed in the Registration Statement, the Time of Sale Prospectus or the Prospectus.

(hh) *Foreign Corrupt Practices Act.* Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries has, in the course of its actions for, or on behalf of, the Company or any of its subsidiaries (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made any direct or indirect unlawful payment to any domestic government official, "foreign official" (as defined in the U.S. Foreign

Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "**FCPA**") or employee from corporate funds; (iii) violated or is in violation of any provision of the FCPA or any applicable non-U.S. anti-bribery statute or regulation; or (iv) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any domestic government official, such foreign official or employee; and the Company and its subsidiaries and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted and maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(ii) Money Laundering Laws. The operations of the Company and its subsidiaries are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "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 Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(jj) **OFAC.** Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, after due inquiry, any director, officer, agent, employee, affiliate or person acting on behalf of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"); and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, or any joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person, or in any country or territory, that currently is the subject to any U.S. sanctions administered by OFAC or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of U.S. sanctions administered by OFAC.

(kk) *Brokers.* Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(l) Forward-Looking Statements. Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement, the Time of Sale Prospectus or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that it was false or misleading.

(mm) *Emerging Growth Company Status.* From the time of the filing of the Registration Statement with the Commission 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").

(nn) *Communications*. The Company (i) has not alone engaged in communications with potential investors in reliance on Section 5(d) of the Securities Act other than Permitted Section 5(d) Communications or Section 5(d) Oral Communications with the consent of the Representatives with entities that are QIBs or IAIs and (ii) has not authorized anyone other than the Representatives to engage in such communications; the Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Marketing Materials, Section 5(d) Oral Communications and Section 5(d) Written Communications; as of the Applicable Time, each Permitted Section 5(d) Communication, when

considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, include an untrue statement of a material fact or 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; and each Permitted Section 5(d) Communication, if any, does not, as of the date hereof, conflict with the information contained in the Registration Statement, the Preliminary Prospectus and the Prospectus.

Clinical Data and Regulatory Compliance. The preclinical tests and clinical trials, and other studies (collectively, "studies") conducted by (00) or on behalf of or sponsored by the Company or any of its subsidiaries or in which the Company or any of its subsidiaries or their products or product candidates have participated were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and all applicable laws and regulations, including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58, 312 and 812; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company and its subsidiaries have no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Time of Sale Prospectuses or the Prospectus; no investigational new drug application filed by or on behalf of the Company or any of its subsidiaries with the U.S. Food and Drug Administration ("FDA") has been terminated or suspended by the FDA, and neither the FDA nor any applicable foreign regulatory agency has commenced, or, to the knowledge of the Company, threatened to initiate, any action to place a clinical hold order on, or otherwise terminate, delay or suspend, any proposed or ongoing studies conducted or proposed to be conducted by or on behalf of the Company or any of its subsidiaries; the Company and its subsidiaries have made all such filings and hold all such Permits as may be required by the FDA or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "Regulatory Agencies"); and the Company and its subsidiaries have fulfilled and performed all of their material obligations with respect to such Permits, and 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 such Permit.

Compliance with Health Care Laws. The Company and its subsidiaries are, and at all times have been, in compliance in all respects with (pp) all applicable Health Care Laws, and have not engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other state health care program or federal health care program, except as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. For purposes of this Agreement, "Health Care Laws" means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; (ii) all applicable federal, state, local and all applicable foreign health care related fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the U.S. Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated pursuant to such statutes; (iii) Medicare (Title XVIII of the Social Security Act); (iv) Medicaid (Title XIX of the Social Security Act); and (v) any and all other applicable health care laws and regulations. Neither the Company nor any of its subsidiaries have received notice of any claim, action, suit, proceeding, hearing, enforcement, audit, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Health Care Laws, and, to the Company's knowledge, no such claim, action, suit, proceeding,

hearing, enforcement, audit, investigation, arbitration or other action is threatened. Neither the Company nor any of its subsidiaries are a party to or have any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any Regulatory Agency or other governmental or regulatory authority. Additionally, neither the Company nor any of its subsidiaries, nor any of their respective employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

Product Manufacturing and Safety Notices. The manufacture of Company products by or on behalf of the Company or any of its (qq)subsidiaries is being conducted in compliance in all material respects with all applicable Health Care Laws, including, without limitation, the FDA's current good manufacturing practice regulations set forth at 21 C.F.R. Parts 210-211 for products sold in the United States, and the respective counterparts thereof promulgated by governmental authorities in countries outside the United States. Except as would not reasonably be expected to result a Material Adverse Effect, neither the Company nor any of its subsidiaries has had any product or manufacturing site (whether Company-owned or that of a contract manufacturer for Company products) subject to a governmental authority (including FDA) shutdown or import or export prohibition, nor received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters," requests to make changes to the Company products processes or operations, or similar correspondence or notice from the FDA or other governmental authority alleging or asserting material noncompliance with any applicable Health Care Laws. To the Company's knowledge, neither the FDA nor any other governmental authority is considering such action. Except as would not, individually or in the aggregate, have or may reasonably be expected to have a Material Adverse Effect: (i) there have been no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, "dear doctor" letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company products (collectively, "Safety Notices") (ii) such Safety Notices, if any, were resolved or closed, and (iii) to the Company's knowledge, there are no material complaints with respect to the Company products that are currently unresolved. To the Company's knowledge, there are no facts that would be reasonably likely to result in (i) a material Safety Notice with respect to the Company products, (ii) a material change in labeling of any the Company products, or (iii) a termination or suspension of marketing or testing of any of the Company products.

(rr) No Rights to Purchase Preferred Stock. The issuance and sale of the Shares as contemplated hereby will not cause any holder of any shares of capital stock, securities convertible into or exchangeable or exercisable for capital stock or options, warrants or other rights to purchase capital stock or any other securities of the Company to have any right to acquire any shares of preferred stock of the Company.

(ss) No Contract Terminations. Neither the Company nor any of its subsidiaries has sent or received any written communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in any preliminary prospectus, the Prospectus or any free writing prospectus, or referred to or described in, or filed as an exhibit to, the Registration Statement, or any document incorporated by reference therein, and no such termination or non-renewal has been threatened by the Company or any of its subsidiaries or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof.

(tt) No rated debt. There are no debt securities or preferred stock issued, or guaranteed by, the Company or any of its subsidiaries that are rated by a "nationally recognized statistical rating organization," as such term is defined in Section 3(a)(62) of the Exchange Act.

(uu) *Dividend Restrictions*. No subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or to any other subsidiary.

Any certificate signed by any officer of the Company or any of its subsidiaries and delivered to any Underwriter or to counsel for the Underwriters in connection with the offering, or the purchase and sale, of the Offered Shares shall be deemed a representation and warranty by the Company or any such subsidiary, as applicable, to each Underwriter as to the matters covered thereby.

The Company has a reasonable basis for making each of the representations set forth in this Section 1. The Company acknowledges that the Underwriters and, for purposes of the opinions to be delivered pursuant to Section 6 hereof, counsel to the Company and counsel to the Underwriters, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

#### Section 2. Purchase, Sale and Delivery of the Offered Shares.

(a) *The Firm Shares.* Upon the terms herein set forth, the Company agrees to issue and sell to the several Underwriters an aggregate of 8,645,000 Firm Shares. On the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Underwriters agree, severally and not jointly, to purchase from the Company the respective number of Firm Shares set forth opposite their names on <u>Schedule A</u>. The purchase price per Firm Share to be paid by the several Underwriters to the Company shall be \$10.1050 per share.

(b) *The First Closing Date.* Delivery of certificates for the Firm Shares to be purchased by the Underwriters and payment therefor shall be made at the offices of Latham & Watkins LLP (or such other place as may be agreed to by the Company and the Representatives) at 9:00 a.m. New York City time, on October 22, 2018, or such other time and date not later than 1:30 p.m. New York City time, on October 22, 2018 as the Representatives shall designate by notice to the Company (the time and date of such closing are called the "**First Closing Date**"). The Company hereby acknowledges that circumstances under which the Representatives may provide notice to postpone the First Closing Date as originally scheduled include, but are not limited to, any determination by the Company or the Representatives to recirculate to the public copies of an amended or supplemented Prospectus or a delay as contemplated by the provisions of Section 11.

(c) *The Optional Shares; Option Closing Date.* In addition, on the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to an aggregate of 1,296,750 Optional Shares from the Company at the purchase price per share to be paid by the Underwriters for the Firm Shares. The option granted hereunder may be exercised at any time and from time to time in whole or in part upon notice by the Representatives to the Company, which notice may be given at any time within 30 days from the date of this Agreement. Such notice shall set forth (i) the aggregate number of Optional Shares as to which the Underwriters are exercising the option and (ii) the time, date and place at which certificates for the Optional Shares will be delivered (which time and date may be simultaneous with, but not earlier than, the First Closing Date; and

in the event that such time and date are simultaneous with the First Closing Date, the term "**First Closing Date**" shall refer to the time and date of delivery of certificates for the Firm Shares and such Optional Shares). Any such time and date of delivery, if subsequent to the First Closing Date, is called an "**Option Closing Date**," shall be determined by the Representatives and shall not be earlier than three or later than five full business days after delivery of such notice of exercise. If any Optional Shares are to be purchased, each Underwriter agrees, severally and not jointly, to purchase the number of Optional Shares (subject to such adjustments to eliminate fractional shares as the Representatives may determine) that bears the same proportion to the total number of Optional Shares to be purchased as the number of Firm Shares set forth on <u>Schedule A</u> opposite the name of such Underwriter bears to the total number of Firm Shares. The Representatives may cancel the option at any time prior to its expiration by giving written notice of such cancellation to the Company.

(d) *Public Offering of the Offered Shares.* The Representatives hereby advise the Company that the Underwriters intend to offer for sale to the public, initially on the terms set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus, their respective portions of the Offered Shares as soon after this Agreement has been executed as the Representatives, in their sole judgment, have determined is advisable and practicable.

## (e) Payment for the Offered Shares.

(i) Payment for the Offered Shares shall be made at the First Closing Date (and, if applicable, at each Option Closing Date) by wire transfer of immediately available funds to the order of the Company.

(ii) It is understood that the Representatives have been authorized, for their own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Shares and any Optional Shares the Underwriters have agreed to purchase. Each of Leerink and Evercore, individually and not as the Representatives of the Underwriters, may (but shall not be obligated to) make payment for any Offered Shares to be purchased by any Underwriter whose funds shall not have been received by the Representatives by the First Closing Date or the applicable Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

(f) Delivery of the Offered Shares. The Company shall deliver, or cause to be delivered, through the facilities of the Depository Trust Company ("DTC") unless the Representatives otherwise instruct, to the Representatives for the accounts of the several Underwriters certificates for the Firm Shares at the First Closing Date, against the irrevocable release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The Company shall also deliver, or cause to be delivered, through the facilities of the DTC unless the Representatives otherwise instruct, to the Representatives for the accounts of the several Underwriters, certificates for the Optional Shares the Underwriters have agreed to purchase at the First Closing Date or the applicable Option Closing Date, as the case may be, against the irrevocable release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The certificates for the Offered Shares shall be registered in such names and denominations as the Representatives shall have requested at least two full business days prior to the First Closing Date (or the applicable Option Closing Date, as the case may be) and shall be made available for inspection on the business day preceding the First Closing Date (or the applicable Option Closing Date, as the case may be) at a location in New York City as the Representatives may designate. Time shall be of the essence, and delivery at the time and place specified in this Agreement is a further condition to the obligations of the Underwriters.

### Section 3. Additional Covenants of the Company. The Company further covenants and agrees with each Underwriter as follows:

(a) Delivery of Registration Statement, Time of Sale Prospectus and Prospectus. The Company shall furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the second business day succeeding the date of this Agreement and during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) Representatives' Review of Proposed Amendments and Supplements. During the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), the Company (i) will furnish to the Representatives for review, a reasonable period of time prior to the proposed time of filing of any proposed amendment or supplement to the Registration Statement, a copy of each such amendment or supplement and (ii) will not amend or supplement the Registration Statement (including any amendment or supplement through incorporation of any report filed under the Exchange Act, other than Exchange Act filings made solely to comply with legal obligations and not to otherwise update any disclosure required by Section 3(g) hereof) without the Representatives' prior written consent, which will not be unreasonably withheld, conditioned or delayed. Prior to amending or supplementing any preliminary prospectus, the Time of Sale Prospectus or the Prospectus, the Company shall furnish to the Representatives for review, a reasonable amount of time prior to the time of filing or use of the proposed amendment or supplement without the Representatives' prior written consent, which will not be unreasonably withheld, conditioned or delayed. Prior to amending or supplement. The Company shall not file or use any such proposed amendment or supplement without the Representatives' prior written consent, which will not be unreasonably withheld, conditioned or delayed. The Company shall 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.

Free Writing Prospectuses. The Company shall furnish to the Representatives for review, a reasonable amount of time prior to the (c) proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto prepared by or on behalf of, used by, or referred to by the Company, and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Representatives' prior written consent, which will not be unreasonably withheld, conditioned or delayed. The Company shall furnish to each Underwriter, without charge, as many copies of any free writing prospectus prepared by or on behalf of, used by or referred to by the Company as such Underwriter may reasonably request. If at any time when a prospectus is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares (but in any event if at any time through and including the First Closing Date) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or 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 prevailing at such time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, as the case may be; provided, however, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Representatives for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such

proposed amended or supplemented free writing prospectus, and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Representatives' prior written consent, which will not be unreasonably withheld, conditioned or delayed.

(d) *Filing of Underwriter Free Writing Prospectuses.* The Company shall not 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 such Underwriter that such Underwriter otherwise would not have been required to file thereunder.

(e) Amendments and Supplements to Time of Sale Prospectus. If the Time of Sale Prospectus is being used to solicit offers to buy the Offered 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 so that the Time of Sale Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, 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, 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, the Company shall (subject to Section 3(b) and Section 3(c) hereof) promptly 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 Time of Sale Prospectus as so amended or supplemented will not include an untrue statement of a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospectus, as amended or supplemented, will no longer conflict with the information contained in the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) Certain Notifications and Required Actions. After the date of this Agreement and until such time as the Underwriters are no longer required to deliver a Prospectus in order to confirm sales of Offered Shares, the Company shall promptly advise the Representatives in writing of: (i) the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus; any free writing prospectus or the Prospectus; (iii) the time and date that any post-effective amendment to the Registration Statement thereto or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus; and (iv) the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus or of any order preventing or suspending the use of any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order as soon as possible. Additionally, the Company agrees that it shall comply with all applicable provisions of Rule 424(b), Rule 433 and Rule 430B under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(g) Amendments and Supplements to the Prospectus and Other Securities Act Matters. If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a

material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading, or if in the opinion of the Representatives or counsel for the Underwriters it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, the Company agrees (subject to Section 3(b) and Section 3(c)) hereof to promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law. Neither the Representatives' consent to, nor delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 3(b) or Section 3(c).

(h) Blue Sky Compliance. The Company shall cooperate with the Representatives and counsel for the Underwriters to qualify or register the Offered Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws of those jurisdictions designated by the Representatives, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Offered Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified. The Company will advise the Representatives promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Offered Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof as soon as possible.

(i) Use of Proceeds. The Company shall apply the net proceeds from the sale of the Offered Shares sold by it substantially in the manner described under the caption "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(j) *Transfer Agent.* The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

(k) *Earnings Statement.* The Company will make generally available to its security holders and to the Representatives as soon as practicable an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company commencing after the date of this Agreement that will satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(I) Continued Compliance with Securities Laws. The Company will comply with the Securities Act and the Exchange Act so as to permit the completion of the distribution of the Offered Shares as contemplated by this Agreement, the Registration Statement, the Time of Sale Prospectus and the Prospectus. Without limiting the generality of the foregoing, the Company will, during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), file on a timely basis with the Commission and Nasdaq all reports and documents required to be filed under the Exchange Act.

(m) *Listing.* The Company will use its best efforts to list, subject to notice of issuance, the Offered Shares on Nasdaq.

(n) Company to Provide Copy of the Prospectus in Form That May be Downloaded from the Internet. If requested by the Representatives, the Company shall cause to be prepared and delivered, at its expense, within one business day from the effective date of this Agreement, to the Representatives an "electronic Prospectus" to be used by the Underwriters in connection with the offering and sale of the Offered Shares. As used herein, the term "electronic Prospectus" means a form of Time of Sale Prospectus, and any amendment or supplement thereto, that meets each of the following conditions: (i) it shall be encoded in an electronic format, satisfactory to the Representatives, that may be transmitted electronically by the Representatives and the other Underwriters to offerees and purchasers of the Offered Shares; (ii) it shall disclose the same information as the paper Time of Sale Prospectus, except to the extent that graphic and image material cannot be disseminated electronically, in which case such graphic and image material shall be replaced in the electronic Prospectus with a fair and accurate narrative description or tabular representation of such material, as appropriate; and (iii) it shall be in or convertible into a paper format or an electronic format, satisfactory to the Representatives, that will allow investors to store and have continuously ready access to the Time of Sale Prospectus at any future time, without charge to investors (other than any fee charged for subscription to the Internet as a whole and for on-line time). The Company hereby confirms that it has included or will include in the Prospectus filed pursuant to EDGAR or otherwise with the Commission and in the Registration Statement at the time it was declared effective an undertaking that, upon receipt of a request by an investor or his or her representative, the Company shall transmit or cause to be transmitted promptly, without charge, a paper copy of the Time of Sale Prospectus.

Agreement Not to Offer or Sell Additional Shares. During the period commencing on and including the date hereof and continuing through and including the 90th day following the date of the Prospectus (such period being referred to herein as the "Lock-up Period"), the Company will not, without the prior written consent of the Representatives (which consent may be withheld in their sole discretion), directly or indirectly: (i) sell, offer to sell, contract to sell or lend any Shares or Related Securities (as defined below); (ii) effect any short sale, or establish or increase any "put equivalent position" (as defined in Rule 16a-1(h) under the Exchange Act) or liquidate or decrease any "call equivalent position" (as defined in Rule 16a-1(b) under the Exchange Act) of any Shares or Related Securities; (iii) pledge, hypothecate or grant any security interest in any Shares or Related Securities; (iv) in any other way transfer or dispose of any Shares or Related Securities; (v) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise; (vi) announce the offering of any Shares or Related Securities; (vii) file any registration statement under the Securities Act in respect of any Shares or Related Securities (other than as contemplated by this Agreement with respect to the Offered Shares); or (viii) publicly announce the intention to do any of the foregoing; provided, however, that the Company may (A) effect the transactions contemplated hereby and (B) issue Shares, options to purchase Shares or restricted stock units, or issue Shares upon exercise of options, pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, provided the recipients thereof provide to the Representatives a signed Lock-Up Agreement substantially in the form of Exhibit A hereto, (C) issue Shares pursuant to the conversion or exchange of convertible or exchangeable securities or the exercise of options, in each case outstanding on the date hereof, (D) file a registration statement on Form S-8 to register Shares issuable pursuant to the terms of a stock option, stock bonus or other stock plan or arrangement described in the Registration Statement, Time of Sale Prospectus and the Prospectus, (E) issue Shares in connection with any joint venture, commercial or collaborative relationship or the acquisition or license by the Company of the securities, businesses, property or other assets of another person or entity or pursuant to any employee benefit plan as assumed by the Company in

connection with any such acquisition; provided, however, that in the case of clause (E), (x) such Shares shall not in the aggregate exceed 10% of the Company's outstanding shares of common stock immediately following the consummation of the offering of the Offered Shares contemplated by this Agreement and (y) the recipients thereof provide to the Representatives a signed Lock-Up Agreement in the form of <u>Exhibit A</u> hereto, and (F) file, supplement, or amend a registration statement or a prospectus pursuant to the Registration Rights Agreement, dated May 27, 2016, by and between the Company and the investors named therein. For purposes of the foregoing, "**Related Securities**" shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for, or convertible into, Shares.

(p) Future Reports to the Representatives. During the period of five years hereafter, the Company will furnish to the Representatives, c/o Leerink Partners LLC, One Federal Street, 37th Floor, Boston, Massachusetts 02110, Attention: Syndicate Department, and c/o Evercore Group L.L.C., 55 East 52nd Street New York, New York 10055, Attention: Equity Capital Markets (i) as soon as practicable after the end of each fiscal year, copies of the Annual Report of the Company containing the balance sheet of the Company as of the close of such fiscal year and statements of income, stockholders' equity and cash flows for the year then ended and the opinion thereon of the Company's independent public or certified public accountants; (ii) as soon as practicable after the filing thereof, copies of each proxy statement, Annual Report on Form 10-K, Quarterly Report on Form 10-Q, Current Report on Form 8-K or other report filed by the Company with the Commission or any securities exchange; and (iii) as soon as available, copies of any report or communication of the Company furnished or made available generally to holders of its capital stock; provided, however, that the requirements of this Section 3(p) shall be satisfied to the extent that such reports, statement, communications, financial statements or other documents are available on EDGAR.

(q) *Investment Limitation.* The Company shall not invest or otherwise use the proceeds received by the Company from its sale of the Offered Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

(r) No Stabilization or Manipulation; Compliance with Regulation M. The Company will not take, and will ensure that no affiliate of the Company will take, directly or indirectly, any action designed to or that might cause or result in stabilization or manipulation of the price of the Shares or any reference security with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and the Company will, and shall cause each of its affiliates to, comply with all applicable provisions of Regulation M.

(s) Enforce Lock-Up Agreements. During the Lock-up Period, the Company will enforce all agreements between the Company and any of its security holders that restrict or prohibit, expressly or in operation, the offer, sale or transfer of Shares or Related Securities or any of the other actions restricted or prohibited under the terms of the form of Lock-up Agreement. In addition, the Company will direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such "lock-up" agreements for the duration of the periods contemplated in such agreements, including, without limitation, "lock-up" agreements entered into by the Company's officers and directors and stockholders pursuant to Section 6(j) hereof.

(t) *Company to Provide Interim Financial Statements.* Prior to the First Closing Date and each applicable Option Closing Date, the Company will furnish the Underwriters, as soon as practicable after they have been prepared by or are available to the Company, a copy of any unaudited

financial statements of the Company for any period subsequent to the period covered by the most recent financial statements appearing in the Registration Statement and the Prospectus.

(u) Amendments and Supplements to Permitted Section 5(d) Communications. If at any time following the distribution of any Permitted Section 5(d) Communication, during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), there occurred or occurs an event or development as a result of which such Permitted Section 5(d) 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 Permitted Section 5(d) Communication to eliminate or correct such untrue statement or omission.

(v) *Emerging Growth Company Status.* 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) the time when a prospectus relating to the Offered Shares is not required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) and (ii) the expiration of the Lock-up Period (as defined herein).

The Representatives, on behalf of the several Underwriters, may, in their sole discretion, waive in writing the performance by the Company of any one or more of the foregoing covenants or extend the time for their performance.

Section 4 Payment of Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Offered Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Shares, (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Offered Shares to the Underwriters, (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Time of Sale Prospectus, the Prospectus, each free writing prospectus prepared by or on behalf of, used by, or referred to by the Company, and each preliminary prospectus, each Permitted Section 5(d) Communication, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Underwriters in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Offered Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Representatives, preparing and printing a "Blue Sky Survey" or memorandum (such "Blue Sky Survey" or memorandum, fees and expenses of counsel not to exceed \$5,000) and a "Canadian wrapper", and any supplements thereto, advising the Underwriters of such qualifications, registrations and exemptions, (vii) the costs, fees and expenses incurred by the Underwriters in connection with determining their compliance with the rules and regulations of FINRA related to the Underwriters' participation in the offering and distribution of the Offered Shares, including any related filing fees and the legal fees of, and disbursements by, counsel to the Underwriters in an amount not to exceed \$20,000, (viii) the costs and expenses of the Company relating to investor presentations on any "road show", any Permitted Section 5(d) Communication or any Section 5(d) Oral Communication undertaken in connection with the offering of the Offered 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, employees and officers of the Company and any such consultants, and 50% of the cost of any aircraft chartered in connection with the road show (the remaining 50% of the cost of such aircraft to be paid by the Underwriters), (ix) the fees and expenses associated with listing the Offered Shares on Nasdaq and (x) all other fees, costs and expenses of the nature referred to in Item 13 of Part II of the Registration Statement. Except as provided in this Section 4 or in Section 7, Section 9 or Section 10 hereof, the Underwriters shall pay their own expenses, including the fees and disbursements of their counsel and their own travel and lodging expenses.

**Section 5. Covenant of the Underwriters.** Each Underwriter severally and not jointly covenants with the Company not to take any action that would result in 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 such Underwriter that otherwise would not, but for such actions, be required to be filed by the Company under Rule 433(d).

Section 6. Conditions of the Obligations of the Underwriters. The respective obligations of the several Underwriters hereunder to purchase and pay for the Offered Shares as provided herein on the First Closing Date and, with respect to the Optional Shares, each Option Closing Date, shall be subject to the accuracy of the representations and warranties on the part of the Company set forth in Section 1 hereof as of the date hereof and as of the First Closing Date as though then made and, with respect to the Optional Shares, as of each Option Closing Date as though then made, to the timely performance by the Company of its covenants and other obligations hereunder, and to each of the following additional conditions:

(a) *Comfort Letter.* On the date hereof, the Representatives shall have received from PricewaterhouseCoopers LLP, independent registered public accountants for the Company, a letter dated the date hereof addressed to the Underwriters, in form and substance satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus, and each free writing prospectus, if any.

(b) *Chief Financial Officer Certificate.* On each of the date hereof, the First Closing Date and each Option Closing Date, the Representatives shall have received a certificate executed by the Chief Financial Officer of the Company, dated as of such date, in form and substance reasonably satisfactory to the Representatives, as to the accuracy of certain data contained in the Registration Statement, the Time of Sale Prospectus and Prospectus.

## (c) Compliance with Registration Requirements; No Stop Order; No Objection from FINRA.

(i) The Company shall have filed the Prospectus with the Commission (including the information previously omitted from the Registration Statement pursuant to Rule 430B under the Securities Act) in the manner and within the time period required by Rule 424(b) under the Securities Act; or the Company shall have filed a post-effective amendment to the Registration Statement containing the information previously omitted from the Registration Statement pursuant to Rule 430B, and such post-effective amendment shall have become effective.

(ii) No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment to the Registration Statement shall be in effect, and no proceedings for such purpose shall have been instituted or threatened by the Commission.

(iii) If a filing has been made with FINRA, FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(d) *No Material Adverse Change.* For the period from and after the date of this Agreement and through and including the First Closing Date and, with respect to any Optional Shares purchased after the First Closing Date, each Option Closing Date, in the judgment of the Representatives there shall not have occurred any Material Adverse Change.

(e) *Opinion of Counsel for the Company.* On each of the First Closing Date and each Option Closing Date the Representatives shall have received the opinion of Cooley LLP, counsel for the Company, dated as of such date, in the form reasonably satisfactory to the Representatives.

(f) Opinions of Intellectual Property Counsel for the Company. On each of the First Closing Date and each Option Closing Date, the Representatives shall have received the opinion of Pepper Hamilton LLP, Intellectual Property counsel for the Company with respect to intellectual property matters, dated as of such date, in the form reasonably satisfactory to the Representatives.

(g) *Opinion of Counsel for the Underwriters.* On each of the First Closing Date and each Option Closing Date the Representatives shall have received the opinion of Latham & Watkins LLP, counsel for the Underwriters in connection with the offer and sale of the Offered Shares, in form and substance satisfactory to the Underwriters, dated as of such date.

(h) *Officers' Certificate.* On each of the First Closing Date and each Option Closing Date, the Representatives shall have received a certificate executed by the Chief Executive Officer or President of the Company and the Chief Financial Officer of the Company, dated as of such date, to the effect set forth in Section 6(c)(ii) and further to the effect that:

(i) for the period from and including the date of this Agreement through and including such date, there has not occurred any Material Adverse Change;

(ii) the representations, warranties and covenants of the Company set forth in Section 1 of this Agreement are true and correct with the same force and effect as though expressly made on and as of such date; and

(iii) the Company has complied with all the agreements hereunder and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such date.

(i) Bring-down Comfort Letter. On each of the First Closing Date and each Option Closing Date the Representatives shall have received from PricewaterhouseCoopers LLP, independent registered public accountants for the Company, a letter dated such date, in form and substance satisfactory to the Representatives, which letter shall: (i) reaffirm the statements made in the letter furnished by them pursuant to Section 6(a), except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the First Closing Date or the applicable Option Closing Date, as the case may be; and (ii) cover certain financial information contained in the Prospectus.

(j) *Lock-Up Agreements.* On or prior to the date hereof, the Company shall have furnished to the Representatives an agreement in the form of Exhibit A hereto from each of the persons listed on Exhibit B hereto, and each such agreement shall be in full force and effect on each of the First Closing Date and each Option Closing Date.

(k) *Rule 462(b) Registration Statement.* In the event that a Rule 462(b) Registration Statement is filed in connection with the offering contemplated by this Agreement, such Rule 462(b) Registration Statement shall have been filed with the Commission on the date of this Agreement and shall have become effective automatically upon such filing.

(I) Additional Documents. On or before each of the First Closing Date and each Option Closing Date, the Representatives and counsel for the Underwriters shall have received such information, documents and opinions as they may reasonably request for the purposes of enabling them to pass upon the issuance and sale of the Offered Shares as contemplated herein, or in order to evidence the accuracy of any of the representations and warranties, or the satisfaction of any of the conditions or agreements, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Offered Shares as contemplated herein and in connection with the other transactions contemplated by this Agreement shall be satisfactory in form and substance to the Representatives and counsel for the Underwriters.

If any condition specified in this Section 6 is not satisfied when and as required to be satisfied, this Agreement may be terminated by the Representatives by notice from the Representatives to the Company at any time on or prior to the First Closing Date and, with respect to the Optional Shares, at any time on or prior to the applicable Option Closing Date, which termination shall be without liability on the part of any party to any other party, except that Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination.

Section 7. Reimbursement of Underwriters' Expenses. If this Agreement is terminated by the Representatives pursuant to Section 6 or Section 12, or if the sale to the Underwriters of the Offered Shares on the First Closing Date is not consummated because of any refusal, inability or failure on the part of the Company to perform any agreement herein or to comply with any provision hereof, the Company agrees to reimburse the Representatives and the other Underwriters (or such Underwriters as have terminated this Agreement with respect to themselves), severally, upon demand for all out-of-pocket expenses that shall have been reasonably incurred by the Representatives and the Underwriters in connection with the proposed purchase and the offering and sale of the Offered Shares, including, but not limited to, fees and disbursements of counsel, printing expenses, travel expenses, postage, facsimile and telephone charges; provided, however, that in the event any such termination is effected after the First Closing Date but prior to any Option Closing Date with respect to the purchase of any Optional Shares, the Company shall only reimburse the Underwriters for all of their out of pocket expenses, including the reasonable fees and disbursements of counsel for the Underwriters, incurred after the First Closing Date in connection with the proposed purchase of any such Optional Shares. For the avoidance of doubt, it is understood that the Company will not pay or reimburse any costs, fees or expenses incurred by any Underwriter that defaults on its obligations to purchase the Offered Shares.

Section 8. Effectiveness of this Agreement. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

#### Section 9. Indemnification.

(a) Indemnification of the Underwriters. The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors, officers, employees and agents, and each person, if any, who controls any Underwriter within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which such Underwriter or such affiliate, director, officer, employee, agent or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Offered Shares have been offered or sold or at common law or otherwise (including in settlement of

any litigation, if such settlement is effected with the written consent of the Company), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing), or the omission or alleged omission to state therein a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading; and to reimburse each Underwriter and each such affiliate, director, officer, employee, agent and controlling person for any and all expenses (including the fees and disbursements of counsel) as such expenses are incurred by such Underwriter or such affiliate, director, officer, employee, agent or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; provided, however, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company by the Representatives in writing expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any such free writing prospectus, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information consists of the information described in Section 9(b) below. The indemnity agreement set forth in this Section 9(a) shall be in addition to any liabilities that the Company may otherwise have.

Indemnification of the Company, its Directors and Officers. Each Underwriter agrees, severally and not jointly, to indemnify and hold (b) harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act, against any loss, claim, damage, liability or expense, as incurred, to which the Company, or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or 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 or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus, that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433 of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement) or the omission or alleged omission to state therein a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, such preliminary prospectus, the Time of Sale Prospectus, such free writing prospectus, such Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement), in reliance upon and in conformity with information relating to such Underwriter furnished to the Company by the Representatives in writing expressly for use therein; and to reimburse the Company, or any such director, officer or controlling person for any and all expenses (including the fees and disbursements of counsel) as such expenses are incurred by the Company, or any such director, officer or controlling person in

connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The Company hereby acknowledges that the only information that the Representatives have furnished to the Company expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing) are the statements set forth in the first two sentences of the first paragraph under the caption "Underwriting—Commissions and Discounts" and the second sentence under the caption "Underwriting—Price Stabilization, Short Positions and Penalty Bids" in the Preliminary Prospectus Supplement and the Final Prospectus Supplement. The indemnity agreement set forth in this Section 9(b) shall be in addition to any liabilities that each Underwriter may otherwise have.

(c) Notifications and Other Indemnification Procedures. Promptly after receipt by an indemnified party under this Section 9 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 9, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve the indemnifying party from any liability which it may have to any indemnified party to the extent the indemnifying party is not materially prejudiced as a proximate result of such failure and shall not in any event relieve the indemnifying party from any liability that it may have otherwise than on account of this indemnity agreement. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; provided, however, that if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 9 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by the Representatives (in the case of counsel for the indemnified parties referred to in Section 9(a) above) or by the Company (in the case of counsel for the indemnified parties referred to in Section 9(b) above)) or (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred.

(d) *Settlements.* The indemnifying party under this Section 9 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 against any loss, claim, damage, liability or expense 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 Section 9(c) hereof, the indemnifying party shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and does not include an admission of fault or culpability or a failure to act by or on behalf of such indemnified party.

Section 10. **Contribution**. If the indemnification provided for in Section 9 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (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 Offered Shares pursuant to this Agreement or (ii) if the allocation provided by clause (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 (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Offered Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total proceeds from the offering of the Offered Shares pursuant to this Agreement (before deducting expenses) received by the Company, and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth on the front cover page of the Prospectus, bear to the aggregate initial public offering price of the Offered Shares as set forth on such cover. The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriters, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 9(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 9(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 10; *provided, however*, that no additional notice shall be required with respect to any action for which notice has been given under Section 9(c) for purposes of indemnification.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 10 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 which does not take account of the equitable considerations referred to in this Section 10.

Notwithstanding the provisions of this Section 10, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by such Underwriter in connection with the Offered Shares underwritten by it and distributed to the public. 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 Underwriters' obligations to contribute pursuant to this Section 10 are several, and not joint, in proportion to their respective underwriting commitments as set forth opposite their respective names on <u>Schedule A</u>. For purposes of this Section 10, each affiliate, director, officer, employee and agent of an Underwriter and each person, if any, who controls an Underwriter within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 11. Default of One or More of the Several Underwriters. If, on the First Closing Date or any Option Closing Date any one or more of the several Underwriters shall fail or refuse to purchase Offered Shares that it or they have agreed to purchase hereunder on such date, and the aggregate number of Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase does not exceed 10% of the aggregate number of the Offered Shares to be purchased on such date, the Representatives may make arrangements satisfactory to the Company for the purchase of such Offered Shares by other persons, including any of the Underwriters, but if no such arrangements are made by such date, the other Underwriters shall be obligated, severally and not jointly, in the proportions that the number of Firm Shares set forth opposite their respective names on Schedule A 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 may be specified by the Representatives with the consent of the non-defaulting Underwriters, to purchase the Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date. If, on the First Closing Date or any Option Closing Date any one or more of the Underwriters shall fail or refuse to purchase Offered Shares and the aggregate number of Offered Shares with respect to which such default occurs exceeds 10% of the aggregate number of Offered Shares to be purchased on such date, and arrangements satisfactory to the Representatives and the Company for the purchase of such Offered Shares are not made within 48 hours after such default, this Agreement shall terminate without liability of any party to any other party, except that the provisions of Section 4, Section 7, Section 9 and Section 10 shall at all times be effective and shall survive such termination. In any such case either the Representatives or the Company shall have the right to postpone the First Closing Date or the applicable Option Closing Date, as the case may be, but in no event for longer than seven days in order that the required changes, if any, to the Registration Statement and the Prospectus or any other documents or arrangements may be effected.

As used in this Agreement, the term "**Underwriter**" shall be deemed to include any person substituted for a defaulting Underwriter under this Section 11. Any action taken under this Section 11 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

Section 12. Termination of this Agreement. Prior to the purchase of the Firm Shares by the Underwriters on the First Closing Date, this Agreement may be terminated by the Representatives by notice given to the Company if at any time: (i) trading or quotation in any of the Company's securities shall have been suspended or limited by the Commission or by Nasdaq, or trading in securities generally on either Nasdaq or the New York Stock Exchange shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges; (ii) a general banking moratorium shall have been declared by any of federal, New York or Pennsylvania authorities; (iii) there shall have occurred any outbreak or escalation of national or

international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Representatives is material and adverse and makes it impracticable to market the Offered Shares in the manner and on the terms described in the Time of Sale Prospectus or the Prospectus or to enforce contracts for the sale of securities; (iv) in the judgment of the Representatives there shall have occurred any Material Adverse Change; or (v) the Company shall have sustained a loss by strike, fire, flood, earthquake, accident or other calamity of such character as in the judgment of the Representatives may interfere materially with the conduct of the business and operations of the Company regardless of whether or not such loss shall have been insured. Any termination pursuant to this Section 12 shall be without liability on the part of (a) the Company to any Underwriter, except that the Company shall be obligated to reimburse the expenses of the Representatives and the Underwriters pursuant to Section 7 hereof or (b) any Underwriter to the Company; *provided, however*, that the provisions of Section 9 and Section 10 shall at all times be effective and shall survive such termination.

Section 13. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Offered Shares pursuant to this Agreement, including the determination of the public offering price of the Offered Shares and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering contemplated hereby and the process leading to such transaction, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advisors to the extent it deemed appropriate.

Section 14. Representations and Indemnities to Survive Delivery. The respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the several Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Offered Shares sold hereunder and any termination of this Agreement.

**Section 15. Notices**. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Representatives:

Leerink Partners LLC

One Federal Street, 37th Floor Boston, Massachusetts 02110 Facsimile: (617) 918-4900 Attention: General Counsel With a copy to: Legal (Facsimile: (617) 918-4664)

	Evercore Group L.L.C. 55 East 52nd Street New York, New York 10055 Attention: Equity Capital Markets
with a copy to:	Latham & Watkins LLP 200 Clarendon Street 27th Floor Boston, Massachusetts 02116 Facsimile: (617) 948-6001 Attention: Peter Handrinos, Esq.
If to the Company:	Aclaris Therapeutics, Inc. 640 Lee Road Suite 200 Wayne, Pennsylvania 19087 Attention: Kamil Ali-Jackson
with a copy to:	Cooley LLP 11951 Freedom Drive 14 <sup>th</sup> Floor Reston, Virginia 20190-5640 Facsimile: (703) 456-8100 Attention: Brian F. Leaf, Esq.

Any party hereto may change the address for receipt of communications by giving written notice to the others.

**Section 16. Successors.** This Agreement will inure to the benefit of and be binding upon the parties hereto, including any substitute Underwriters pursuant to Section 11 hereof, and to the benefit of the affiliates, directors, officers, employees, agents and controlling persons referred to in Section 9 and Section 10, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "**successors**" shall not include any purchaser of the Offered Shares as such from any of the Underwriters merely by reason of such purchase.

**Section 17. Partial Unenforceability**. The invalidity or unenforceability of any section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph or provision hereof. If any section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

**Section 18. Governing Law Provisions**. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("**Related Proceedings**") may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City

of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a "**Related Judgment**"), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

**Section 19. Waiver of Jury Trial**. The Company hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

**Section 20. General Provisions.** This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

Each of the parties hereto acknowledges that it is a sophisticated business person who was adequately represented by counsel during negotiations regarding the provisions hereof, including, without limitation, the indemnification provisions of Section 9 and the contribution provisions of Section 10, and is fully informed regarding said provisions. Each of the parties hereto further acknowledges that the provisions of Section 9 and Section 10 hereof fairly allocate the risks in light of the ability of the parties to investigate the Company, its affairs and its business in order to assure that adequate disclosure has been made in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, each free writing prospectus and the Prospectus (and any amendments and supplements to the foregoing), as contemplated by the Securities Act and the Exchange Act.

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms.

Very truly yours,

# ACLARIS THERAPEUTICS, INC.

By: /s/ Neal Walker

Name:Neal WalkerTitle:President and CEO

[Signature Page to Underwriting Agreement]

The foregoing Underwriting Agreement is hereby confirmed and accepted by the Representatives in New York, New York as of the date first above written.

# LEERINK PARTNERS LLC

**EVERCORE GROUP L.L.C.** Acting individually and as the Representatives of the several Underwriters named in the attached <u>Schedule A</u>.

# LEERINK PARTNERS LLC

By: /s/ Stuart R. Nayman

Name:Stuart R. NaymanTitle:Managing Director

# EVERCORE GROUP L.L.C.

By: /s/ James T. Chandler Name: James T. Chandler Title: Senior Managing Director

[Signature Page to Underwriting Agreement]

#### Schedule A

Underwriters	Number of Firm Shares to be Purchased
Leerink Partners LLC	3,198,650
Evercore Group L.L.C.	2,766,400
Cantor Fitzgerald & Co.	1,729,000
Guggenheim Securities, LLC	950,950
Total	8,645,000

# Free Writing Prospectuses Included in the Time of Sale Prospectus

None

Number of Firm Shares: 8,645,000

Price per Share to the public: \$10.7500

Number of Optional Shares: 1,296,750

# Permitted Section 5(d) Communications

None

October , 2018

Leerink Partners LLC Evercore Group, L.L.C. As Representatives of the Several Underwriters

c/o Leerink Partners LLC One Federal Street, 37th Floor Boston, Massachusetts 02110

c/o Evercore Group, L.L.C. 55 East 52<sup>nd</sup> Street New York, New York 10055

RE: Aclaris Therapeutics, Inc. (the "Company")

Ladies & Gentlemen:

The undersigned is an owner of shares of common stock, par value \$0.00001 per share, of the Company ("Shares") or of securities convertible into or exchangeable or exercisable for Shares. The Company proposes to conduct a public offering of Shares (the "Offering") for which Leerink Partners LLC ("Leerink") and Evercore Group, L.L.C. (together with Leerink, the "Representatives") will act as representatives of the underwriters. The undersigned recognizes that the Offering will benefit the Company and the undersigned. The undersigned acknowledges that you are relying on the representations and agreements of the undersigned contained in this letter agreement in conducting the Offering and, at a subsequent date, in entering into an underwriting agreement (the "Underwriting Agreement") and other underwriting arrangements with the Company with respect to the Offering.

Annex A sets forth definitions for capitalized terms used in this letter agreement that are not defined in the body of this letter agreement. Those definitions are a part of this letter agreement.

In consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby agrees that, during the Lock-up Period, the undersigned will not (and will use best efforts to cause any Family Member not to), subject to the exceptions set forth in this letter agreement, without the prior written consent of the Representatives, which may withhold their consent in their sole discretion:

- Sell or Offer to Sell any Shares or Related Securities currently or hereafter owned either of record or beneficially (as defined in Rule 13d-3 under the Exchange Act) by the undersigned or such Family Member,
- enter into any Swap,
- make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any Shares or Related Securities, or cause to be filed a registration

statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or

• publicly announce any intention to do any of the foregoing.

The foregoing will not apply to the registration of the offer and sale of the Shares, and the sale of the Shares to the underwriters, in each case as contemplated by the Underwriting Agreement. In addition, the foregoing restrictions shall not apply to (i) the transfer of Shares or Related Securities by gift or by will or intestate succession to the legal representative, heir, beneficiary or any Family Member or to a trust whose beneficiaries consist exclusively of one or more of the undersigned and/or Family Member(s), (ii) transfers or dispositions of the undersigned's Shares or Related Securities to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held by the undersigned or any Family Member, (iii) distributions of the undersigned's Shares or Related Securities to partners, members, stockholders or other equityholders of the undersigned, provided that any such transfer or distribution shall not involve a disposition for value and (iv) the transfer of Shares or Related Securities by operation of law, including pursuant to a domestic order or negotiated divorce settlement; *provided*, *however*, that in any such case, it shall be a condition to such transfer that:

- each transferee or distributee executes and delivers to the Representatives an agreement in form and substance satisfactory to the Representatives stating that such transferee or distributee is receiving and holding such Shares and/or Related Securities subject to the provisions of this letter agreement and agrees not to Sell or Offer to Sell such Shares and/or Related Securities, engage in any Swap or engage in any other activities restricted under this letter agreement except in accordance with this letter agreement (as if such transferee or distributee had been an original signatory hereto), and
- prior to the expiration of the Lock-up Period, no public disclosure or filing under the Exchange Act by any party to the transfer (donor, donee, transferor or transferee) shall be required, or made voluntarily, reporting a reduction in beneficial ownership of Shares in connection with such transfer.

Furthermore, notwithstanding the restrictions imposed by this letter agreement, the undersigned may (i) exercise an option to purchase Shares granted under any equity incentive plan or stock purchase plan of the Company, existing as of the date hereof and described in the Prospectus, *provided* that the underlying Shares shall continue to be subject to the restrictions on transfer set forth in this letter agreement, (ii) establish a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of Shares, provided that such plan does not provide for any transfers of Shares or Related Securities during the Lock-up Period and the entry into such plan is not publicly disclosed, including in any filings under the Exchange Act, during the Lock-up Period, (iii) subject to the restrictions set forth in the following paragraph, transfer or dispose of Shares acquired in the open market following the Offering, provided that no public disclosures or filing under the Exchange Act shall be required, or made voluntarily, or (iv) transfer Shares (A) to the Company as forfeitures to satisfy tax withholding obligations of the undersigned in connection with the vesting or exercise of equity awards by the undersigned pursuant to the Company's equity incentive plans existing as of the date hereof and described in the Prospectus, (B) pursuant to a net exercise or cashless exercise by the undersigned of outstanding equity awards pursuant to the Company's equity incentive plans existing as of the date hereof and described in the scales (B) shall be subject to the restrictions set forth in this letter agreement, or (C) pursuant to a bona fide third-party tender offer for all outstanding shares of the Company, merger, consolidation or other similar transaction made to all holders of the Company's securities involving a change of control of the Company (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of common stock or other such securities in connection with such transaction, or vote any common stock or other such securities in favor of any such transaction), *provided* that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such securities held by the undersigned shall remain subject to the provisions of this letter agreement; *provided* that, in the case of a transfer pursuant to clause (A) or (B) above, if the undersigned is required to make a filing under the Exchange Act reporting a reduction in beneficial ownership of Shares during the Lock-up Period, the undersigned shall include a statement in such report to the effect that the purpose of such transfer was to cover tax obligations of the undersigned in connection with such exercise.

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 Shares or Related Securities held by the undersigned and the undersigned's Family Members, if any, except in compliance with the foregoing restrictions.

With respect to the Offering only, the undersigned waives any registration rights relating to registration under the Securities Act of the offer and sale of any Shares and/or any Related Securities owned either of record or beneficially by the undersigned, including any rights to receive notice of the Offering.

The undersigned confirms that the undersigned has not, and has no knowledge that any Family Member has, directly or indirectly, taken any action designed to or that might reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale of the Shares. The undersigned will not, and will cause any Family Member not to take, directly or indirectly, any such action.

Whether or not the Offering occurs as currently contemplated or at all depends on market conditions and other factors. The Offering will only be made pursuant to the Underwriting Agreement, the terms of which are subject to negotiation between the Company and you.

The undersigned hereby represents and warrants that the undersigned has full power, capacity and authority to enter into this letter agreement. This letter agreement is irrevocable and will be binding on the undersigned and the successors, heirs, personal representatives and assigns of the undersigned.

This letter agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

If (i) the Company notifies the Representatives in writing that it does not intend to proceed with the Offering, (ii) the Underwriting Agreement is not executed before November 30, 2018 or (iii) the Underwriting Agreement (other than the provisions thereof that survive termination) terminates or is terminated prior to payment for and delivery of the Firm Shares, then in each case, this letter agreement shall automatically, and without any action on the part of any other party, terminate and be of no further force and effect, and the undersigned shall automatically be released from the obligations under this letter agreement.

Printed Name of Person Signing

(Indicate capacity of person signing if signing as custodian or trustee, or on behalf of an entity)

#### Annex A

#### Certain Defined Terms <u>Used in Lock-up Agreement</u>

For purposes of the letter agreement to which this Annex A is attached and of which it is made a part:

"Call Equivalent Position" shall have the meaning set forth in Rule 16a-1(b) under the Exchange Act.

"Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

- "Family Member" shall mean the spouse of the undersigned, an immediate family member of the undersigned or an immediate family member of the undersigned's spouse, in each case living in the undersigned's household or whose principal residence is the undersigned's household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or otherwise). "Immediate family member" as used above shall have the meaning set forth in Rule 16a-1(e) under the Exchange Act.
- "Lock-up Period" shall mean the period beginning on the date hereof and continuing through the close of trading on the date that is 90 days after the date of the Prospectus (as defined in the Underwriting Agreement).

"Put Equivalent Position" shall have the meaning set forth in Rule 16a-1(h) under the Exchange Act.

"**Related Securities**" shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for or convertible into Shares.

"Securities Act" shall mean the Securities Act of 1933, as amended.

"Sell or Offer to Sell" shall mean to:

- · sell, offer to sell, contract to sell or lend,
- effect any short sale or establish or increase a Put Equivalent Position or liquidate or decrease any Call Equivalent Position
- · pledge, hypothecate or grant any security interest in, or
- · in any other way transfer or dispose of,

in each case whether effected directly or indirectly.

"Swap" shall mean any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise.

Capitalized terms not defined in this Annex A shall have the meanings given to them in the body of this lock-up agreement.

# **Directors:**

William D. Humphries Anand Mehra, M.D. Christopher Molineaux Andrew Powell Stephen Tullman Andrew Schiff Bryan Reasons Neal Walker

# Officers:

Neal Walker Christopher Powala Stuart Shanler Kamil Ali-Jackson Frank Ruffo Brett Fair David Gordon

# Others:

2007 Irrevocable Trust of Stephen A. Tullman Christopher V. Powala Aclaris Irrevocable Trust

**B-1** 



Brian F. Leaf T + 1 703 456 8053 bleaf@cooley.com

October 18, 2018

Aclaris Therapeutics, Inc. 640 Lee Road, Suite 200 Wayne, Pennsylvania 19087

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the offering by Aclaris Therapeutics, Inc., a Delaware corporation (the "*Company*"), of up to 9,941,750 shares (the "*Shares*") (including up to 1,296,750 shares that may be sold pursuant to the underwriters' exercise of an option to purchase additional shares) of the Company's common stock, par value \$0.00001 per share (the "*Common Stock*"), pursuant to a Registration Statement on Form S-3 (Registration No. 333-214384) (the "*Initial Registration Statement*"), filed with the Securities and Exchange Commission (the "*Commission*") under the Securities Act of 1933, as amended (the "*Act*"), a Registration Statement on Form S-3 (Registration No. 333-227880) filed with the Commission pursuant to Rule 462(b) of Regulation C promulgated under the Act (together with the Initial Registration Statement, the "*Registration Statement*"), the related prospectus dated November 14, 2016 (the "*Base Prospectus*") and the prospectus supplement dated October 17, 2018, filed with the Commission pursuant to Rule 424(b) under the Act (together with the Base Prospectus, the "*Prospectus*").

In connection with this opinion, we have examined and relied upon the Registration Statement, the Prospectus, the Company's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, each as currently in effect, and the originals or copies certified to our satisfaction of such records, documents, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have assumed the genuineness and authenticity of all documents submitted to us as originals, the conformity to originals of all documents submitted to us as copies thereof, the accuracy, completeness and authenticity of certificates of public officials, and the due execution and delivery of all documents where due execution and delivery are a prerequisite to the effectiveness thereof.

Our opinion is expressed only with respect to the General Corporation Law of the State of Delaware. We express no opinion to the extent that any other laws are applicable to the subject matter hereof and express no opinion and provide no assurance as to compliance with any federal or state securities law, rule or regulation.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that the Shares, when sold in accordance with the Registration Statement and the related Prospectus, will be validly issued, fully paid and nonassessable.

ONE FREEDOM SQUARE, RESTON TOWN CENTER, 11951 FREEDOM DRIVE, RESTON, VA 20190-5656 T: (703) 456-8000 F: (703) 456-8100 WWW.COOLEY.COM

We consent to the reference to our firm under the caption "Legal Matters" in the Prospectus and to the filing of this opinion as an exhibit to a current report of the Company on Form 8-K to be filed with the Commission for incorporation by reference into the Registration Statement.

Very truly yours,

# **COOLEY LLP**

By: /s/ Brian F. Leaf Brian F. Leaf



# ACLARIS ANNOUNCES PROPOSED PUBLIC OFFERING OF COMMON STOCK

**WAYNE, PA, October 17, 2018** — Aclaris Therapeutics, Inc. (Nasdaq: ACRS), a dermatologist-led, biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet patient needs in aesthetic and medical dermatology and immunology, today announced that it intends to offer and sell, subject to market conditions, shares of its common stock in an underwritten public offering. All of the shares of common stock to be sold in the offering will be offered by Aclaris. Aclaris also intends to grant the underwriters a 30-day option to purchase up to an additional 15% of the shares of its common stock offered in the public offering on the same terms and conditions. The offering is subject to market conditions, and there can be no assurance as to whether or when the offering may be completed, or the actual size or terms of the offering.

Leerink Partners and Evercore ISI are acting as joint book-running managers for the offering.

A shelf registration statement relating to the shares of common stock offered in the public offering described above was filed with the Securities and Exchange Commission (SEC) on November 2, 2016 and declared effective by the SEC on November 14, 2016. The offering will be made only by means of a written prospectus and prospectus supplement that form a part of the registration statement. A preliminary prospectus supplement and accompanying prospectus relating to the offering will be filed with the SEC and will be available on the SEC's website at www.sec.gov. Copies of the preliminary prospectus supplement and the accompanying prospectus, when available, may also be obtained by contacting Leerink Partners LLC, Attention: Syndicate Department, One Federal Street, 37th Floor, Boston, MA 02110, telephone: (800) 808-7525, ext. 6132, or by email at syndicate@leerink.com; or Evercore Group L.L.C., Attention: Equity Capital Markets, 55 East 52nd Street, 36th Floor, New York, New York 10055, by telephone at 888-474-0200, or by email at ecm.prospectus@evercore.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy the securities being offered, nor shall there be any sale of the securities being offered in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

#### About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet needs in dermatology, both aesthetic and medical, and immunology. Aclaris' focus on market segments with no FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised seborrheic keratoses and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata, and vitiligo.

### **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Aclaris Therapeutics, Inc., including statements about Aclaris' anticipated public offering and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all and such other factors as are set forth in the risk factors detailed in Aclaris' Annual Report on Form 10-K for the year ended December 31, 2017 and other filings Aclaris makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent Aclaris' views as of the date hereof. Aclaris anticipates that subsequent events and developments will cause Aclaris' views to change. However, while Aclaris may elect to update these forward-looking statements at some point in the future, Aclaris specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Aclaris' views as of any date subsequent to the date hereof.

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Contact:

Aclaris Contact Michael Tung, M.D. Senior Vice President Corporate Strategy/Investor Relations 484-329-2140 mtung@aclaristx.com

Media Contact Sheila Kennedy Vice President, Corporate Communications 484-321-5559 media@aclaristx.com



# ACLARIS ANNOUNCES PRICING OF PUBLIC OFFERING OF COMMON STOCK

**WAYNE, PA, October 17, 2018** — Aclaris Therapeutics, Inc. (Nasdaq: ACRS), a dermatologist-led, biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet patient needs in aesthetic and medical dermatology and immunology, today announced the pricing of its underwritten public offering of 8,645,000 shares of its common stock at a price to the public of \$10.75 per share. In addition, Aclaris has granted to the underwriters a 30-day option to purchase up to 1,296,750 additional shares of common stock at the public offering price, less the underwriting discount. The gross proceeds from the offering to Aclaris are expected to be approximately \$92.9 million, before deducting underwriting discounts and commissions and offering expenses, but excluding any exercise of the underwriters' option. The offering is expected to close on or about October 22, 2018, subject to customary closing conditions.

Leerink Partners and Evercore ISI are acting as joint book-running managers for the offering. Cantor is acting as lead manager for the offering. Guggenheim Securities is acting as co-manager for the offering.

A shelf registration statement relating to this offering was filed with the Securities and Exchange Commission (SEC) on November 2, 2016 and declared effective by the SEC on November 14, 2016. The offering is being made only by means of a written prospectus and prospectus supplement that form a part of the registration statement. A preliminary prospectus supplement and accompanying prospectus relating to the offering has been filed with the SEC and is available on the SEC's website at www.sec.gov. A final prospectus supplement and accompanying prospectus will be filed with the SEC. When available, copies of the final prospectus supplement and the accompanying prospectus may also be obtained by contacting Leerink Partners LLC, Attention: Syndicate Department, One Federal Street, 37th Floor, Boston, MA 02110, telephone: (800) 808-7525, ext. 6132, or by email at syndicate@leerink.com; or Evercore Group L.L.C., Attention: Equity Capital Markets, 55 East 52nd Street, 36th Floor, New York, New York 10055, by telephone at 888-474-0200, or by email at ecm.prospectus@evercore.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy the securities being offered, nor shall there be any sale of the securities being offered in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

#### About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative therapies to address significant unmet needs in dermatology, both aesthetic and medical, and immunology. Aclaris' focus on market segments with no FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised seborrheic keratoses and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata, and vitiligo.

#### **Forward-Looking Statements**

Any statements in this press release about future expectations, plans and prospects for Aclaris Therapeutics, Inc., including statements about Aclaris' public offering related to expected gross proceeds and anticipated closing date, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and the completion of the public offering on the anticipated terms or at all and such other factors as are set forth in the risk factors detailed in Aclaris' Annual Report on Form 10-K for the year ended December 31, 2017 and other filings Aclaris makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent Aclaris' views as of the date hereof. Aclaris anticipates that subsequent events and developments will cause Aclaris' views to change. However, while Aclaris may elect to update these forward-looking statements at some point in the future, Aclaris specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Aclaris' views as of any date subsequent to the date hereof.

## ###

Contact:

Aclaris Contact Michael Tung, M.D. Senior Vice President Corporate Strategy/Investor Relations 484-329-2140 mtung@aclaristx.com

Media Contact Sheila Kennedy Vice President, Corporate Communications 484-321-5559 media@aclaristx.com In the preliminary prospectus supplement filed pursuant to Rule 424(b)(5) in connection with a public offering of common stock by Aclaris Therapeutics, Inc. (the "Company"), the Company provided the following overview of the Company's business and the following risk factors as updates to the information provided in the Company's previous periodic filings with the Securities and Exchange Commission.

## **Company Overview**

We are a dermatologist-led biopharmaceutical company focused on identifying, developing and commercializing innovative therapies to address significant unmet needs in medical and aesthetic dermatology and immunology. Our lead product ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, is a proprietary formulation of high-concentration hydrogen peroxide topical solution that has been approved by the U.S. Food and Drug Administration, or FDA, as an office-based prescription treatment for raised seborrheic keratosis, or SK, a common non-malignant skin tumor. The FDA approved our New Drug Application, or NDA, for ESKATA for the treatment of raised SKs in December 2017. We also submitted a Marketing Authorization Application, or MAA, for ESKATA in select countries in the European Union in July 2017. We are also developing another high-concentration formulation of hydrogen peroxide, A-101 45% Topical Solution, as a prescription treatment for common warts, also known as verruca vulgaris. Additionally, in 2015, we inlicensed exclusive, worldwide rights to certain inhibitors of the Janus kinase, or JAK, family of enzymes, for specified dermatological conditions, including alopecia areata, or AA, vitiligo and androgenetic alopecia, or AGA, also known as male or female pattern baldness. In 2016, we acquired additional intellectual property rights for the development and commercialization of certain JAK inhibitors for specified dermatological conditions. We have also entered into an agreement to acquire RHOFADE (oxymetazoline hydrochloride) cream, 1% and additional intellectual property from Allergan, as described further below under "— Recent Developments." RHOFADE is approved for the topical treatment of persistent facial erythema, or redness, associated with rosacea in adults. We intend to continue to in-license or acquire additional drug candidates and technologies to build a fully integrated dermatology company.

We have been developing our sales, marketing and product distribution capabilities for ESKATA in order to support our commercial launch in the United States, which occurred in May 2018. We have also hired a targeted field sales force of 50 sales representatives which we believe will allow us to reach the approximately 6,000 health care providers in the United States with the highest potential for using ESKATA.

We are developing A-101 45% Topical Solution for the treatment of common warts. In June 2017, we commenced two Phase 2 clinical trials, WART-202 and WART-203, of A-101 45% topical solution to assess the dose frequency in adult and pediatric patients with common warts. Both trials evaluated the safety and efficacy of A-101 45% Topical Solution as compared to placebo, or vehicle. The two randomized, double-blind, vehicle-controlled trials were designed to evaluate the effects of dose frequency and to explore additional clinical endpoints that will be further evaluated in a planned Phase 3 development program. We enrolled a total of 316 patients at 34 investigational centers in the United States across both trials. In January 2018, we reported top line results from these two Phase 2 clinical trials of A-101 45% Topical Solution. In March 2018, we reported final results, which included a 3-month drug-free follow-up phase, from the WART-203 clinical trial. In addition, in April 2018, we concluded the WART-202 clinical trial, in which we evaluated a different dosing regimen from the one used in the WART-203 clinical trial. In both of these clinical trials, patients treated with A-101 45% Topical Solution achieved clinically and statistically significant outcomes for the primary, secondary and exploratory endpoints of the trial. Based on the results from these clinical trials, we held an end of Phase 2 meeting with the FDA and are using a twice-weekly dosing regimen in our Phase 3 clinical trials in the second half of 2019 and, if those results are positive, to submit an NDA to the FDA thereafter.

We are developing our JAK inhibitor drug candidate ATI-501, which we licensed from Rigel Pharmaceuticals, Inc., or Rigel, as an oral treatment for AA. AA is an autoimmune dermatologic condition typically characterized by patchy non-scarring hair loss on the scalp and body. More severe forms of AA include total scalp hair loss, known

as alopecia totalis, and total hair loss on the scalp and body, known as alopecia universalis. We submitted an investigational new drug application, or IND, to the FDA for ATI-501 for the treatment of AA in October 2016. Since the filing of the IND, we have conducted several Phase 1 clinical trials to evaluate the pharmacokinetic and pharmacodynamic, or PK/PD, properties of various formulations of ATI-501. Based on the results from these clinical trials, we selected an oral suspension and have initiated a Phase 2 dose-response clinical trial of ATI-501.

We are developing ATI-502, which we also licensed from Rigel, as a topical treatment for AA, vitiligo and AGA, as well as atopic dermatitis, a common form of eczema. We submitted an IND to the FDA for ATI-502 for the treatment of AA in July 2017. The following table summarizes the status of our ongoing Phase 2 clinical trials of ATI-501 and ATI-502, including their indications, trial objectives and expected timing for initiation and receipt of preliminary results:

					Preliminary Results
Drug Candidate and Name of Trial	Indication	Objective	Patients	Initiation	Expected
<u>ATI-501</u>					
AUAT-201	AA	Dose-ranging	80	Initiated	2H 2019
<u>ATI-502</u>					
AA-201	AA	Dose-ranging	120	Initiated	1H 2019
AA-202	AA	PK/PD	11	Initiated	1H 2018(1)
AUATB-201	AA (Eyebrow)	Open-label study	12	Initiated	2H 2018
VITI-201	Vitiligo	Open-label study	33	Initiated	1H 2019
AGA-201	AGA	Open-label study	24	Initiated	1H 2019
AD-201	Atopic Dermatitis	Open-label study	30	Initiated	Mid-2019

#### (1) AA-202 interim data reported in June 2018.

In August 2017, we acquired Confluence Life Sciences, Inc., our subsidiary that we have renamed Aclaris Life Sciences, Inc. This acquisition added small molecule drug discovery and preclinical development capabilities that allow us to bring early-stage research and development activities in-house that we previously outsourced to third parties. We also acquired several preclinical drug candidates as part of this acquisition, including additional JAK inhibitors known as "soft" JAK inhibitors, inhibitors of the MK-2 signaling pathway and inhibitors of interleukin-2-inducible T cell kinase, or ITK. We expect to submit an IND to the FDA for ATI-450, an MK-2 inhibitor, in mid-2019, and for our soft JAK inhibitors and ITK inhibitors in the second half of 2019. We are considering developing ATI-450 for the treatment of rheumatoid arthritis, psoriasis, hidradenitis suppurativa, cryopyrin-associated periodic syndrome, and pyoderma gangrenosum. We are considering developing our soft-JAK inhibitors for the treatment of dermatological conditions, including atopic dermatitis, vitiligo and AA. We are considering developing our ITK inhibitors for the treatment of psoriasis, inflammatory dermatoses and inflammatory bowel disease.

#### **Recent Developments**

#### Acquisition of RHOFADE

On October 15, 2018, we entered into an Asset Purchase Agreement, or the APA, with Allergan, pursuant to which we have agreed to acquire the worldwide rights to RHOFADE, as well as additional intellectual property. The acquisition includes an exclusive license to certain intellectual property for RHOFADE. In addition, Allergan has agreed to provide transition support services to us.

Pursuant to the APA, and upon the terms and subject to the conditions thereof, we are required to pay Allergan total cash consideration of \$65.0 million, including \$58.5 million to be paid at the closing and \$6.5 million to be placed in escrow, plus the book value of Allergan's inventory of RHOFADE commercial product and samples, which we estimate to be approximately \$1 million. We have also agreed to pay Allergan a one-time payment of \$5.0 million

upon the achievement of a specified development milestone related to the potential development of an additional dermatology product. In addition, we have agreed to pay Allergan specified royalty payments, ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related to a particular product, such as RHOFADE, have expired or, if later, ten years from the closing date of the acquisition. In addition, we have agreed to assume the rights and obligations of Allergan related to RHOFADE, including the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Members of our management team, including Neal Walker, Frank Ruffo, Christopher Powala and Stuart Shanler, as well as Stephen Tullman, the chairman of our board of directors, are former stockholders of Vicept Therapeutics, Inc., and Dr. Shanler is also a current member of Aspect Pharmaceuticals, LLC. In their capacities as current or former holders of equity interests in these entities, these individuals may be entitled to receive a portion of the potential future payments payable by us to Allergan.

The completion of the acquisition is subject to the satisfaction or waiver of a number of customary closing conditions in the APA, including the receipt of regulatory approval, the absence of certain governmental restraints and the absence of a material adverse effect on us or the RHOFADE business. We expect to close the acquisition in the fourth quarter of 2018.

Allergan received approval from the FDA in January 2017 to market RHOFADE for the topical treatment of persistent facial redness associated with rosacea in adults, and the product became commercially available in the United States in May 2017. Based on independent third-party prescription data, we estimate that there were approximately 50,000 RHOFADE prescriptions filled during the six months ended December 31, 2017 and another approximately 55,000 prescriptions filled during the six months ended June 30, 2018.

Based on information provided to us by Allergan, we estimate that RHOFADE net revenues, consisting of gross revenues less promotional discounts and allowances, were approximately \$17.5 million for the twelve months ended June 30, 2018, with the majority of these net revenues generated in the second half of 2017. The decrease in net revenues for the six months ended June 30, 2018 compared to the second half of 2017 was the result of decreased promotional efforts by Allergan during 2018, following a restructuring program announced by Allergan in January 2018. Historical RHOFADE revenues for any periods prior to the closing of the acquisition are not necessarily indicative of future revenues once we begin to market RHOFADE. We expect to commence marketing of RHOFADE after the closing of the acquisition.

The preliminary financial data of RHOFADE included in this prospectus supplement has been prepared by, and is the responsibility of, our management and has not been reviewed or audited by our independent registered public accounting firm. The preliminary financial data represent the most current information available to us as of the date of this prospectus supplement and are subject to completion of audit and review procedures that could result in significant changes to the estimated amounts. Accordingly, undue reliance should not be placed on such preliminary data. We expect to report audited RHOFADE revenues for the year ended December 31, 2017 and unaudited revenues for the six months ended June 30, 2018, as well as unaudited pro forma financial information, in a Current Report on Form 8-K to be filed following the closing of the acquisition, in accordance with SEC requirements. Accordingly, our independent auditors do not express an opinion or any other form of assurance with respect to this preliminary data.

We expect to be able to achieve synergies from the addition of RHOFADE to our product portfolio by leveraging our existing sales, marketing and product distribution capabilities for ESKATA, which we began marketing in the United States in the second quarter of 2018. As prescriptions for RHOFADE remained relatively stable during the first half of 2018 compared to the second half of 2017, despite reduced promotional efforts from Allergan, we expect prescriptions may increase over the long-term as we actively market the product to potential prescribers. However, the number of prescriptions and promotional discount and allowances may fluctuate from quarter to quarter as we integrate RHOFADE in our product portfolio. We estimate that there is significant overlap among the target audience of healthcare professionals who could be prescribers of both ESKATA and RHOFADE. In addition, we believe that we have a strong understanding of the potential market opportunity for RHOFADE as a result of certain members of our management team having been involved in its development prior to acquisition of the

product by Allergan in 2011. However, if we are unable to successfully integrate RHOFADE effectively, our business will be adversely affected.

In connection with the APA, we have agreed to exclusively license from Allergan a family of U.S. patents and applications relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which expire between January 2024 and May 2028. Following the closing of the acquisition, we will also own a family of patents and applications in the United States, the European Union and other major foreign markets that cover certain cream formulations of oxymetazoline, including RHOFADE, which expires in December 2031. We also will own a family of patents and applications in the United States, the European Union and other major foreign markets relating to methods of treating facial erythema associated with rosacea by topically administering once or twice daily 1% or 1.5% oxymetazoline, which expires in June 2035. We have also agreed to exclusively sublicense, on a royalty-free basis, from Allergan rights under certain patents and applications owned by a third party in the United States, the European Union and other major markets to make, use or sell oxymetazoline for the treatment of rosacea or another skin condition known as purpura, in each case by application to the skin, that would expire between May 2024 and May 2025.

## Loan and Security Agreement with Oxford

On October 15, 2018, we entered into a Loan and Security Agreement with Oxford Finance LLC, or Oxford. The Loan and Security Agreement provides for up to \$65.0 million in term loans. Of the \$65.0 million, \$30.0 million is available for draw until the earlier of October 31, 2018 or an event of default. The remaining \$35.0 million will become available for draw beginning on the closing date of the RHOFADE acquisition and ending on the earlier of March 31, 2019 or an event of default.

#### Preliminary Financial Data

As of September 30, 2018, we estimate that we had approximately \$134 million in cash, cash equivalents and marketable securities. We also expect net revenues from sales of ESKATA for the three months ended September 30, 2018 to be approximately \$0.5 million. These estimates are preliminary since our final reviewed financial statements as of and for the three months ended September 30, 2018 are not yet available.

The preliminary financial data included in this prospectus supplement has been prepared by, and is the responsibility of, our management. There can be no assurance that our cash, cash equivalents and marketable securities or our net revenues from sales of ESKATA as of and for the three months ended September 30, 2018 will not differ from these estimates when our financial statements for the period are finalized and reviewed, including as a result of our quarterly close and review procedures. Any such changes could be material.

Our independent registered public accounting firm, PricewaterhouseCoopers LLP, has not audited, reviewed, compiled or performed any procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

# **Risk Factors**

#### Risks Related to Our Acquisition of RHOFADE and Loan and Security Agreement with Oxford

#### We may not close the acquisition or realize the anticipated benefits from our acquisition of RHOFADE.

We may not close the acquisition of RHOFADE. The completion of the acquisition is subject to the satisfaction or waiver of a number of closing conditions in the APA, including the receipt of regulatory approval, the absence of certain governmental restraints and the absence of a material adverse effect on us or the RHOFADE business. Even if we do close the acquisition, the success of our acquisition of RHOFADE will depend, in large part, on our ability to realize operating synergies from combining RHOFADE with our portfolio of drug candidates and ESKATA.

The failure to successfully integrate and manage the challenges presented by the integration process may result in our failure to achieve some or all of the anticipated benefits of the acquisition. Potential difficulties that may be encountered include the following:

- · complexities associated with managing an additional commercial-stage drug;
- training our sales force to market both ESKATA and RHOFADE;

• current and prospective employees may experience uncertainty regarding their future roles with our company, which might adversely affect our ability to retain, recruit and motivate key personnel;

• our due diligence processes in connection with the acquisition may fail to identify significant problems, risks, liabilities or other shortcomings or challenges associated with the RHOFADE assets, including problems, risks, liabilities or other shortcomings or challenges with respect to intellectual property, product quality and safety and other known and unknown liabilities; and

• performance shortfalls as a result of the diversion of management's attention caused by completing the acquisition and integrating RHOFADE.

If any of these events were to occur, our ability to maintain relationships with customers, suppliers and employees or our ability to achieve the anticipated benefits of the acquisition could be adversely affected, or could reduce our future earnings or otherwise adversely affect our business and financial results and, as a result, adversely affect the market price of our common stock.

#### We may not be able to generate sufficient cash to service our indebtedness, including the Loan and Security Agreement with Oxford.

We have entered into a Loan and Security Agreement with Oxford, pursuant to which we can draw \$30.0 million until October 31, 2018 and can draw an additional \$35.0 million beginning on the closing date of our acquisition of RHOFADE until March 31, 2019. Our obligations under the Loan and Security Agreement are secured by substantially all of our assets except for our intellectual property, and we may not encumber our intellectual property without Oxford's prior written consent. The Loan and Security Agreement contains negative covenants restricting our activities, including limitations on dispositions, mergers or acquisitions, incurring indebtedness or liens, paying dividends or making investments and other specified business transactions. The Loan and Security Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms.

Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the covenants and conditions of the Loan and Security Agreement, including our failure to achieve the minimum revenue covenants, could result in an event of default, which could result in an acceleration of amounts due under the Loan and Security Agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and Oxford could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business.

### **Risks Related to our Business and Intellectual Property**

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

The development and commercialization of new drugs is highly competitive. We face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from many different sources, including major pharmaceutical, biotechnology and specialty pharmaceutical companies, academic institutions and governmental agencies and public and private research institutions.

With respect to ESKATA for the treatment of raised SKs, we are aware of two biopharmaceutical companies developing drug candidates which target SK, and another company that currently markets a line of cosmetic products targeting skin conditions, including SK. We are also aware of early research being conducted with Akt inhibitors as a potential treatment for SK.

With respect to RHOFADE for the treatment of persistent facial redness due to rosacea, we are aware of one other drug that shares this indication. MIRVASO (brimonidine) topical gel, 0.33%, which was approved in 2013, is currently marketed by Galderma Laboratories, L.P.

With respect to A-101 45% Topical Solution for the treatment of common warts, we are aware of four companies developing drug candidates for the treatment of common warts. In addition, other drugs have been used off-label as treatments for common warts. We could also encounter competition from over-the-counter treatments for common warts.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than ESKATA or any other drug that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for our drug, which could result in our competitors establishing a strong market position before we are able to enter the market.

With respect to ATI-501 and ATI-502 for the treatment of AA, we anticipate competing with sensitizing agents such as diphencyprone, and topical, intralesional and systemic corticosteroids, which have been found to occasionally reduce symptoms of AA. Other treatments utilized for patchy AA include anthralin and minoxidil solution. We may also compete with companies developing chemical agents to be used in topical immunotherapies, as well as companies developing biologics, immunosuppressive agents, laser therapy, phototherapy, other JAK inhibitors and prostaglandin analogues to treat AA.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical development, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

# If we are unable to obtain and maintain patent protection for our drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drug candidates may be impaired.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our drug candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our drug candidates.

The patent prosecution process is expensive and time-consuming, however, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The United States Patent Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications that we own, or license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Even if our patent applications that we own or license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or drugs in a non-infringing manner. For example, the patents and patent applications that we exclusively licensed from Columbia University that are primarily directed to methods of treating hair loss disorders with JAK inhibitors may not issue or may issue with claims directed to the use of specific JAK inhibitors, which may not be relevant to the JAK inhibitors we intend to commercialize or the JAK inhibitors that our competitors may commercialize.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result

in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Our issued U.S. patents, with claims directed to treatment of SK and acrochordons with high-concentration hydrogen peroxide of at least 23%, including ESKATA and A-101 45% Topical Solution, are scheduled to expire in 2022, and our issued U.S. formulation patent with claims directed to highconcentration hydrogen peroxide formulations, including ESKATA and A-101 45% Topical Solution, and methods of use is scheduled to expire in 2035. The issued U.S. patents that we have agreed to exclusively license from Allergan relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which cover the approved use of RHOFADE, expire between January 2024 and May 2028. The issued U.S. patent that covers cream formulations of oxymetazoline, including RHOFADE, expires in December 2031. The issued U.S. patents relating to methods of treating facial erythema associated with rosacea by topically administering once or twice daily 1% or 1.5% oxymetazoline expire in June 2035. The patents and applications that we have agreed to exclusively sublicense from Allergan that may relate to RHOFADE expire between May 2024 and May 2025. Certain issued U.S. patents relating to our JAK inhibitors, ATI-501 and ATI-502, are scheduled to expire in 2023 and additional U.S. patents, with claims specifically directed to such JAK inhibitors, are scheduled to expire in 2030. The issued U.S. and Japanese patents that we exclusively licensed from Columbia University with claims directed to the use of third party JAK inhibitors for the treatment of hair loss disorders, including AA and AGA, and inducing hair growth, expire in 2031. We currently do not have any patents issued directed to our "soft" JAK inhibitors, but any claims that may issue would expire in 2038. Our issued U.S. patent covering our lead inhibitors of the MK-2 signaling pathway inhibitor, expires in 2034 and other issued patents covering different MK-2 signaling pathway inhibitors expire in 2031 and 2032. Our issued patents covering our novel inhibitors of ITK expire between 2035 and 2038. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

# We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court.

Competitors may infringe our issued patents or other intellectual property. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar administrative proceedings outside the United States, in parallel with litigation or, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our drug candidates. Such a loss of patent protection would harm our business.

In such a proceeding, a court or administrative board may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any such proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may find it impractical or undesirable to enforce our intellectual property against some third parties. For instance, we are aware of third parties that have marketed high-concentration hydrogen peroxide solutions over the internet for the treatment of SK and

warts. These parties do not appear to have regulatory authority, and we have not authorized them in any way to market these products. However, to date we have refrained from seeking to enforce our intellectual property rights against these third parties due to the transient nature of their activities.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

We are aware that a third party generic pharmaceutical company completed a Phase 3 clinical trial in March 2018 evaluating the reduction in erythema in adults with moderate to severe facial erythema associated with rosacea with a 1% oxymetazoline topical cream in comparison to an oxymetazoline reference listed drug. While conducting such a clinical trial may not be an act of patent infringement in the United States, such a clinical trial could serve as the basis for the third party to file an Abbreviated New Drug Application, or ANDA, or 505(b)(2) application for a generic of RHOFADE that relies in whole or in part on studies conducted by Allergan, which could trigger a potential patent infringement lawsuit. If we were to bring a patent infringement lawsuit against such a third party for infringing any of the U.S. patents relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline that we have agreed to exclusively license from Allergan, we may be required to join Allergan as a party to such a lawsuit. In addition, if we were to bring a patent infringement lawsuit against a third party for infringing certain patents that we have agreed to sublicense from Allergan relating to the use of oxymetazoline for treating rosacea or purpura by topical application, we may also be required to join Allergan and another third party as parties to such a lawsuit.

With respect to ATI-501 and ATI-502, if we do not elect to exercise our first right to do so, Rigel may enforce the licensed patents relating to ATI-501 and ATI-502 against any infringing third party in the field of dermatology. In addition, Rigel has the first right, but not the obligation, to enforce the licensed patents relating to ATI-501 and ATI-502 against any infringing party outside of the field of dermatology. With respect to the licensed patents from Columbia University, Columbia University has the first right to initiate, control and defend any proceedings related to the validity, enforceability or infringement of the licensed patents from Columbia University, and in doing so, has no obligation to assert more than one licensed patent in one jurisdiction against a third party. With respect to the licensed patent rights relating to an infringement of the licensed patent rights against any infringing third party.

# The RHOFADE patents that we have agreed to exclusively license from Allergan are subject to a cross-license agreement with a third party, which will place obligations and limitations on our ability to prosecute, maintain and enforce such patents solely as they relate to an alpha adrenoreceptor agonist that is not oxymetazoline.

We have agreed to exclusively license from Allergan a family of U.S. patents and applications relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which expire between January 2024 and May 2028. This patent family covers the approved use of RHOFADE. This patent family is also subject to an exclusive license granted by Allergan to a third party, which will place obligations and limitations on our ability to prosecute, maintain and enforce such patents solely as they relate to an alpha adrenoreceptor agonist that is not oxymetazoline.

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

Filing, prosecuting and defending patents on our drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. For example, the use of ESKATA for the treatment of raised SKs is currently covered by patents in the United States, Australia, India and New Zealand, but not in the European Union

or other countries. The use of A-101 45% Topical Solution for the treatment of warts is currently covered by issued patents in the United States, Australia, India and New Zealand, but not in the European Union or other countries. A U.S. patent is issued, and patent applications are pending in the United States, the European Union and other foreign countries directed to high-concentration hydrogen peroxide formulations, including ESKATA and A-101 45% Topical Solution and methods of use. With respect to RHOFADE, the family of patents and applications relating to methods of treating erythema resulting from rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which expire between January 2024 and May 2028, is not filed outside of the United States. Accordingly, the patent protection for RHOFADE outside of the United States is based upon a family of patents and applications in the United States, the European Union and other major foreign markets that cover certain cream formulations of oxymetazoline, including RHOFADE, which expires in December 2031 and a family of patents and applications in the United States, the European Union and other major foreign markets relating to methods of treating facial erythema associated with rosacea by topically administering once or twice daily 1% or 1.5% oxymetazoline, which expires in June 2035. RHOFADE may also be covered by certain patents and applications in the United States, the European Union and other major foreign markets that expire between May 2024 and May 2025, which we have agreed to exclusively sublicense from Allergan.

Our JAK inhibitors, ATI-501 and ATI-502, are currently covered in patents and applications in the United States, the European Union, and other major foreign markets. Additionally, U.S. and Japanese patents have issued in the patent portfolio licensed from Columbia University, which are directed to the use of certain third party JAK inhibitors for the treatment of hair loss disorders and applications are pending in the United States, the European Union, Japan and South Korea. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our invention in such countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our drug candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Many countries, including European Union countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

# The validity, scope and enforceability of any of our patents that cover ESKATA, RHOFADE, A-101 45% Topical Solution or any of our other drug candidates can be challenged by competitors.

The likelihood that a third party will challenge our patents covering ESKATA or RHOFADE is increased now that these products have received marketing approval from the FDA. The challenge may come in the form of a patent office proceeding, such as an inter partes review, challenging the validity of the patents or a district court proceeding, such as a paragraph IV litigation arising out of the filing of an ANDA.

If a third party files an ANDA or 505(b)(2) application for a generic of ESKATA or RHOFADE, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved drug

candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with ESKATA or RHOFADE. We are aware that a third party generic pharmaceutical company completed a Phase 3 clinical trial in March 2018 evaluating the reduction in erythema in adults with moderate to severe facial erythema associated with rosacea with a 1% oxymetazoline topical cream in comparison to an oxymetazoline reference listed drug. Such a clinical trial could serve as the basis for filing an ANDA or 505(b)(2) application for a generic of RHOFADE that relies in whole or in part on studies conducted by Allergan, triggering the potential for a paragraph IV certification and subsequent patent infringement lawsuit. Any such lawsuit could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement and the approval of a generic version of RHOFADE sooner than anticipated.

If A-101 45% Topical Solution, our JAK inhibitors, or any of our other drug candidates advance through development or is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio covering these drug candidates. Any such challenge could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement.