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As confidentially submitted to the Securities and Exchange Commission on May 14, 2015

Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Aclaris Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	2834 (Primary Standard Industrial Classification Code Number)	46-0571712 (I.R.S. Employer Identification Number)
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**101 Lindenwood Drive, Suite 400
Malvern, PA 19355
(484) 324-7933**

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

**Neal Walker
President and Chief Executive Officer
Aclaris Therapeutics, Inc.
101 Lindenwood Drive, Suite 400
Malvern, PA 19355
(484) 324-7933**

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

Copies to:

**Brent B. Siler
Divakar Gupta
Brian F. Leaf
Cooley LLP
11951 Freedom Drive
Reston, VA 20190
(703) 456-8000**

**Kamil Ali-Jackson
Chief Legal Officer
Aclaris Therapeutics, Inc.
101 Lindenwood Drive,
Suite 400
Malvern, PA 19355
(484) 324-7933**

**Peter N. Handrinos
Nathan Ajiashvili
Latham & Watkins LLP
John Hancock Tower
200 Clarendon Street
Boston, MA 02116
(617) 948-6000**

**Approximate date of commencement of proposed sale to the public:
As soon as practicable after the effective date of this registration statement.**

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 under the Securities Exchange Act of 1934. (Check one):

Large accelerated filer

Accelerated filer

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

Smaller reporting company

CALCULATION OF REGISTRATION FEE

Title of Securities being Registered	Proposed Maximum Aggregate Offering Price⁽¹⁾⁽²⁾	Amount of Registration Fee
Common Stock, \$0.00001 par value per share	\$	\$

⁽¹⁾ In accordance with Rule 457(o) under the Securities Act of 1933, as amended, the number of shares being registered and the proposed maximum offering price per share are not included in this table.

⁽²⁾ Estimated solely for purposes of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act.

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

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

SUBJECT TO COMPLETION, DATED MAY 14, 2015

PRELIMINARY PROSPECTUS

Shares



Aclaris Therapeutics, Inc.

Common Stock

We are offering _____ shares of our common stock. This is our initial public offering and no public market currently exists for our common stock. We expect the initial public offering price to be between \$ _____ and \$ _____ per share. We intend to apply to list our common stock on The NASDAQ Global Market under the symbol "ACRS."

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933 and will be subject to reduced public company reporting requirements. See "Prospectus Summary — Implications of Being an Emerging Growth Company."

Investing in our common stock involves a high degree of risk. Please read "Risk Factors" beginning on page 10 of this prospectus.

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

	<u>PER SHARE</u>	<u>TOTAL</u>
Public offering price	\$	\$
Underwriting discount and commissions ⁽¹⁾	\$	\$
Proceeds to us, before expenses	\$	\$

⁽¹⁾ See "Underwriting" in this prospectus for a description of compensation payable to the underwriters.

Delivery of the shares of common stock is expected to be made on or about _____, 2015. We have granted the underwriters an option for a period of 30 days to purchase an additional _____ shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$ _____ million, and the total proceeds to us, before expenses, will be \$ _____ million.

Jefferies

Citigroup

William Blair

Prospectus dated _____, 2015

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You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us or to which we have referred you. We have not authorized anyone to provide you with information that is different from that contained in such prospectuses. We are offering to sell shares of our common stock, and seeking offers to buy shares of our common stock, only in jurisdictions where such offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

Until and including _____, 2015, 25 days after the date of this prospectus, all dealers that buy, sell or trade our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to unsold allotments or subscriptions.

For investors outside of the United States: neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our common stock, you should carefully read this entire prospectus, including our financial statements and the related notes thereto and the information set forth under the sections "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Unless the context otherwise requires, we use the terms "Aclaris," "company," "we," "us" and "our" in this prospectus to refer to Aclaris Therapeutics, Inc.

Our Business

We are a clinical-stage specialty pharmaceutical company focused on identifying, developing and commercializing innovative and differentiated topical drugs to address significant unmet needs in dermatology. Our lead drug candidate, A-101, is a proprietary high-concentration hydrogen peroxide topical solution that we are developing as a prescription treatment for seborrheic keratosis, or SK, a common non-malignant skin tumor. We have completed three Phase 2 clinical trials of A-101 in over 300 patients with SK. In these trials, following one or two applications of A-101, we observed clinically relevant and statistically significant improvements in clearing SK lesions on the face, trunk and extremities of the body. Clinically relevant means that the observed results suggest a potential meaningful medical benefit, and statistically significant means that there is a low statistical probability, typically less than 5%, that the observed results occurred by chance alone. We plan to commence three Phase 3 clinical trials of A-101 in patients with SK in the second half of 2015 and, if the results of these trials are favorable, to submit a New Drug Application, or NDA, for A-101 for the treatment of SK to the U.S. Food and Drug Administration, or FDA, in the first half of 2016. We also intend to develop A-101 as a prescription treatment for common warts and A-102, a proprietary gel dosage form of hydrogen peroxide, as a prescription treatment for SK and common warts. In addition, we intend to in-license or acquire additional drug candidates for other dermatological conditions to build a fully integrated dermatology company.

SK lesions are among the most common non-malignant skin tumors and one of the most frequent diagnoses made by dermatologists. SK lesions typically have a waxy, scaly, slightly elevated appearance, and multiple lesions are often present. Though the lesions are non-malignant, patients often elect to have their condition treated by a dermatologist, either because the lesions have become inflamed or because the patient feels they are cosmetically unattractive. SK lesions are usually treated by cryosurgery, electrodesiccation, curettage or excision. Each of these methods may be painful or can result in pigmentary changes or scarring at the treatment site. No drugs have been approved by the FDA for the treatment of SK.

A study published in the Journal of The American Academy of Dermatology in 2006 estimated that SK affects over 83 million people in the United States. Based on a market survey we commissioned in 2014, we estimate that there are 18.5 million patient visits to dermatologists for SK and dermatologists perform approximately 8.3 million procedures to remove SK lesions annually in the United States. We estimate that the cost of these procedures to third-party payors and patients is more than \$1.2 billion annually.

Management Experience

Our management team has extensive experience in dermatological product development from drug discovery through commercialization, with experience as practicing dermatologists and in leadership roles at a number of dermatology companies. Members of our management team founded and led Vicept Therapeutics, Inc., a dermatology company that was acquired by Allergan, Inc. in 2011. In addition, several of our management team members worked together at CollaGenex Pharmaceuticals, Inc., a dermatology-focused specialty pharmaceutical company that was acquired by Galderma Laboratories, LP in 2008, and Trigenesis Therapeutics, Inc., a dermatology company that was acquired by Dr. Reddy's Laboratories Inc. in 2004. We believe that the experience of our management team and our broad network of relationships with leaders

within the industry and medical community provides us with insight into product development and identification of other commercial opportunities in dermatology.

Strategy

Our goal is to develop and commercialize innovative and differentiated dermatology products that address significant unmet medical needs. The key components of our strategy to achieve this goal are to:

- § complete clinical development and obtain regulatory approval for A-101 for the treatment of SK;
- § develop A-101 for the treatment of common warts and develop our other drug candidates;
- § build a specialized sales and marketing organization; and
- § in-license or acquire additional drug candidates to build a fully integrated dermatology company.

Our Drug Candidates

We have utilized our experience to establish a pipeline of drug candidates that we believe will address significant unmet needs in dermatology. Our pipeline of drug candidates is summarized in the table below:

Drug Candidate	Preclinical	Phase 1	Phase 2	Phase 3
A-101 (Topical solution for treatment of SK)	[Arrow spanning Preclinical, Phase 1, and Phase 2]			★
A-101 (Topical solution for treatment of common warts)	[Arrow spanning Preclinical and Phase 1]		◆	
A-102 (Gel dosage form for treatment of SK)	[Arrow in Preclinical]			
A-102 (Gel dosage form for treatment of common warts)	[Arrow in Preclinical]			

- ★ Plan to commence Phase 3 clinical trials in second half of 2015
- ◆ Toxicology studies ongoing; plan to commence Phase 2 clinical trials in second half of 2015

Our Lead Drug Candidate: A-101 for the Treatment of Seborrheic Keratosis

We are developing A-101, our proprietary high-concentration hydrogen peroxide topical solution, for the treatment of SK. SK lesions typically have a waxy, scaly, slightly elevated appearance, and multiple lesions are often present. Though the lesions are non-malignant, patients often elect to have their condition treated by a dermatologist, either because the lesions have become inflamed or because the patient feels they are cosmetically unattractive.

Limitations of Current Treatment Options for Seborrheic Keratosis

There are currently no FDA-approved drugs for the treatment of SK. However, dermatologists typically choose SK treatment based on a number of factors, including disease severity, patient characteristics and patient preference. Cryosurgery, which involves spraying liquid nitrogen at a temperature of negative 320 degrees Fahrenheit directly onto the SK lesions, is used in approximately two-thirds of treated SK patients. Depending on the severity of the patient's condition, more than one cryosurgery treatment is typically required to remove all of the targeted lesions. Adverse effects experienced by patients using cryosurgery

include permanent hypopigmentation, or loss of skin color, hyperpigmentation, or darkening of the skin, scarring, pain and edema, or swelling.

Other treatments include curettage, or scraping, as well as electrodesiccation and excision. We estimate that each of these treatments is used for 5% to 10% of treated SK patients. Curettage involves scraping SK lesions off with the use of a tool known as a curette. As a result, this procedure typically leads to bleeding, may result in infection and requires a longer time for the skin to heal. Electrodesiccation is a form of electrosurgery that involves the use of an electric needle to burn off the SK lesion. Electrodesiccation is labor- and time-intensive, can require local anesthesia and can lead to bleeding, infection and hyperpigmentation. With an excision procedure, the lesion is removed with a scalpel but remains intact for biopsy in cases where a definitive diagnosis has not been made. This procedure requires local anesthesia, can lead to infection and is more expensive than other treatment options. In addition, there are other dermatological treatments that are used less frequently.

Benefits of A-101

- § **Potential to be the First FDA-Approved Drug Treatment for SK.** There are currently no FDA-approved drugs for the treatment of SK. If A-101 is approved by the FDA, it has the potential to be the first drug approved for the treatment of SK in the United States, thereby providing dermatologists confidence in A-101 as a treatment option.
- § **Attractive Efficacy Profile.** In three clinical trials conducted to date in over 300 patients with A-101, we have observed clinically relevant and statistically significant clearance of SK lesions on the face, trunk and extremities after one or two applications.
- § **Non-invasive Treatment with Favorable Safety Profile.** In each of our clinical trials, A-101 was well tolerated and caused minimal discomfort, with most patients experiencing only mild, transient tingling upon application. We believe A-101, if approved, will be an attractive treatment option for SK patients seeking an alternative that is non-invasive and reduces the risk of pigmentary changes, scarring, bleeding and other adverse side effects associated with current treatment procedures.
- § **Ease of Administration.** If approved, we expect that A-101 will be administered using a single-use, self-contained, pre-filled, disposable pen-type applicator as an in-office treatment, without the need for anesthesia. After the initial diagnosis by a dermatologist, we expect that A-101 will be appropriate for administration by non-physician staff, thereby freeing up physician time.

Clinical Development

In November 2013, we commenced our first Phase 2 clinical trial for A-101 for the treatment of SK with 35 enrolled subjects with four SK lesions on the trunk. We evaluated three concentrations of A-101, 25.0%, 32.5% and 40.0%, in this trial. We completed this trial in June 2014 and observed clinically relevant and statistically significant results in the clearance of SK lesions on the trunk for both the 32.5% and 40.0% concentrations of A-101, as compared to vehicle, after one or two applications.

In June 2014, we commenced our second Phase 2 clinical trial for the treatment of SK with 172 enrolled subjects with four SK lesions on the trunk or extremities. We evaluated two concentrations of A-101, 32.5% and 40.0%, in this trial. We completed this trial in December 2014 and observed clinically relevant and statistically significant results in the clearance of SK lesions on the trunk and extremities for both the 32.5% and 40.0% concentrations of A-101, as compared to vehicle, after one or two applications.

In October 2014, we commenced our third Phase 2 clinical trial for A-101 for the treatment of SK with 119 enrolled subjects with a single SK lesion on the face. We evaluated two concentrations of A-101, 32.5% and 40.0%, in this trial. We completed the trial in March 2015 and observed clinically relevant and statistically significant results in the clearance of SK lesions on the face for both the 32.5% and 40.0% concentrations of A-101, as compared to vehicle, after one or two applications.

We submitted the results from these three Phase 2 clinical trials to the FDA and held an end-of-Phase 2 meeting with them in May 2015. Based on the feedback we received from the FDA at this meeting, we plan to commence three Phase 3 clinical trials of A-101 in patients with SK lesions on the face trunk and

extremities in the second half of 2015. If the results of the Phase 3 clinical trials are favorable, we intend to submit our NDA for A-101 for the treatment of SK to the FDA in the first half of 2016 and build a specialty sales force to market the product to dermatologists in the United States. We have also requested scientific advice from the European Medicines Agency, or EMA, for A-101 for the treatment of SK. We plan to seek a collaborator to commercialize A-101, if approved, in the European Union. We have the exclusive right to commercialize A-101, if approved, throughout the world.

We also plan to develop A-101 for the treatment of common warts. We are conducting toxicology studies and plan to commence Phase 2 clinical trials of A-101 for the treatment of common warts in the second half of 2015. In addition to A-101, we are also developing A-102, a proprietary topical gel dosage form of hydrogen peroxide, for the treatment of both SK and common warts.

Intellectual Property

Our intellectual property portfolio contains issued patents directed to methods of use for A-101. Our issued patents begin to expire in 2022, subject to any applicable patent term adjustment or extension. Our intellectual property portfolio also contains provisional patent applications directed to, among other things, formulations and methods of use for A-101 and a single-use, self-contained, pre-filled, disposable pen-type applicator. Our pending U.S. provisional patent applications, if they issue as patents, would be expected to expire beginning in 2035. We intend to file two non-provisional patent applications in the second quarter of 2015 for our formulations and methods of use for A-101 and our pen-type applicator.

Financing History

Since inception, we have financed our operations through private placements of our redeemable convertible preferred stock with several investors, including funds affiliated with Vivo Capital, Fidelity Biosciences and Sofinnova Ventures, providing total gross proceeds of \$31.5 million.

Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware before deciding to invest in our common stock. These risks are discussed more fully in the "Risk Factors" section of this prospectus. These risks include the following:

- § We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- § Even if this offering is successful, we will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.
- § We are early in our development efforts and have only one drug candidate, A-101 for the treatment of SK, for which we have conducted clinical trials. If we are unable to successfully develop, receive regulatory approval for and commercialize A-101 for the treatment of SK or any other drug candidates, or experience significant delays in doing so, our business will be harmed.
- § We expect third-party payors generally will not cover the use of our drug candidates for the treatment of SK and, accordingly, our success will be dependent upon the willingness of patients to pay out of pocket for procedures using these drug candidates.
- § Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- § If we are unable to establish sales, marketing and distribution capabilities for A-101 or any other drug candidate that may receive regulatory approval, we may not be successful in commercializing those drug candidates if and when they are approved.

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

Corporate Information

We were incorporated under the laws of the State of Delaware in July 2012. Our principal executive offices are located at 101 Lindenwood Drive, Suite 400, Malvern, PA 19355 and our telephone number is (484) 324-7933. Our website address is www.aclaristx.com. The information contained on our website is not incorporated by reference into this prospectus, and you should not consider any information contained on, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock.

We have proprietary rights to a number of trademarks used in this prospectus which are important to our business, including the Aclaris Therapeutics trademark. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. All other trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of relief from some of the reporting requirements and other burdens that are otherwise applicable generally to public companies. These provisions include:

- § presentation of only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- § exemption from the auditor attestation requirement on the effectiveness of our internal control over financial reporting;
- § reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements; and
- § no requirements for non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions for up to five years or such earlier time that we no longer qualify as an emerging growth company. We would cease to be an emerging growth company if we have more than \$1.0 billion in annual revenue, have more than \$700 million in market value of our capital stock held by non-affiliates or issue more than \$1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens. For example, we have taken advantage of the reduced reporting requirements with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus, and have taken advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. To the extent that we take advantage of these reduced burdens, the information that we provide stockholders may be different than you might obtain from other public companies in which you hold equity interests.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

THE OFFERING

Common stock offered by us	shares
Common stock to be outstanding immediately after this offering	shares
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to additional shares of our common stock.
Use of proceeds	<p>We estimate that the net proceeds to us from this offering, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, will be \$ million, assuming the shares are offered at \$ per share, which is the midpoint of the estimated price range set forth on the cover page of this prospectus.</p> <p>We anticipate that the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will be used to complete our three planned Phase 3 clinical trials and seek regulatory approval of A-101 for the treatment of SK; to fund continued research and development of A-101 for the treatment of common warts and A-102 for the treatment of SK and common warts, including completion of our planned Phase 2 clinical trials for this indication; and to fund other research and development activities, including development of A-102 for the treatment of SK and common warts, as well as for working capital and other general corporate purposes, including to pursue our strategy to in-license or acquire additional drug candidates. See "Use of Proceeds" for additional information.</p>
Directed share program	<p>At our request, the underwriters have reserved up to shares of common stock, or % of the shares being offered by this prospectus (excluding the shares of common stock that may be issued upon the underwriters' exercise of their option to purchase additional shares), for sale at the initial public offering price to our directors, officers and employees and certain other persons associated with us, as designated by us.</p> <p>The number of shares available for sale to the general public will be reduced to the extent that these individuals purchase all or a portion of the reserved shares. Any reserved shares not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus. For further information regarding our directed share program, please see "Underwriting."</p>
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Proposed NASDAQ Global Market symbol

"ACRS."

The number of shares of our common stock that will be outstanding after this offering is based on 36,761,057 shares of common stock outstanding as of January 31, 2015, after giving effect to the conversion of shares of our redeemable convertible preferred stock outstanding as of January 31, 2015 into an aggregate of 27,341,057 shares of our common stock upon the closing of this offering, and excludes:

- § 1,725,961 shares of our common stock issuable upon the exercise of stock options outstanding under our 2012 equity compensation plan as of January 31, 2015, at a weighted average exercise price of \$0.35 per share; and
- § shares of our common stock reserved for future issuance under our 2015 equity incentive plan, which will become effective upon the closing of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

Except as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, assumes or gives effect to:

- § a -for- reverse stock split of our common stock expected to be completed prior to the closing of this offering;
- § no exercise of the outstanding options described above; and
- § no exercise of the underwriters' option to purchase additional shares of common stock in this offering.

SUMMARY FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes thereto included elsewhere in this prospectus and the "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. We have derived the statement of operations data for the years ended December 31, 2013 and 2014 and the balance sheet data as of December 31, 2014 from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future.

	<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2014</u>
	<u>(in thousands, except per share data)</u>	
Statement of Operations Data:		
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	3,488	6,507
General and administrative	1,769	2,026
Total operating expenses	5,257	8,533
Loss from operations	(5,257)	(8,533)
Interest income	21	16
Net loss	(5,236)	(8,517)
Accretion of redeemable convertible preferred stock to redemption value	(1,740)	(2,054)
Net loss attributable to common stockholders	\$ (6,976)	\$ (10,571)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.87)	\$ (1.78)
Weighted average common shares outstanding, basic and diluted	3,731	5,934
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		\$ (0.30)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)		28,468

The following table presents our summary balance sheet data as of December 31, 2014:

- § on an actual basis;
- § on a pro forma basis to give effect to the conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 27,341,057 shares of our common stock, which will occur upon the closing of this offering; and
- § on a pro forma as adjusted basis to give further effect to our sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	As of December 31, 2014		
	Actual	Pro Forma (in thousands)	Pro Forma As Adjusted
Balance Sheet Data:			
Cash, cash equivalents and marketable securities	\$ 16,648	\$ 16,648	\$
Working capital	14,883	14,883	
Total assets	17,377	17,377	
Redeemable convertible preferred stock	36,677	—	
Total stockholders' equity (deficit)	(20,755)	15,922	

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. Each increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, working capital, total assets and total stockholders' equity by \$ _____ million, assuming no change in the assumed initial public offering price per share and after deducting the estimated underwriting discounts and commissions. This pro forma as adjusted information is illustrative only and will depend on the actual initial public offering price and other terms of this offering determined at pricing.

RISK FACTORS

Investing in our common stock involves a high degree of risk. Before you invest in our common stock, you should carefully consider the following risks, as well as general economic and business risks, and all of the other information contained in this prospectus. Any of the following risks could have a material adverse effect on our business, operating results and financial condition and cause the trading price of our common stock to decline, which would cause you to lose all or part of your investment. When determining whether to invest, you should also refer to the other information contained in this prospectus, including our financial statements and the related notes thereto.

Risks Related to Our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

We are a clinical-stage specialty pharmaceutical company with limited operating history. Since inception, we have incurred significant net losses. We incurred net losses of \$5.2 million and \$8.5 million for the years ended December 31, 2013 and 2014, respectively. As of December 31, 2014, we had an accumulated deficit of \$20.7 million. We have financed our operations to date with \$31.5 million in gross proceeds raised in private placements of redeemable convertible preferred stock. We have no products approved for commercialization and have never generated any revenue.

We have devoted substantially all of our financial resources and efforts to development of our lead drug candidate, A-101 for the treatment of SK, including preclinical studies and clinical trials. We have completed three Phase 2 clinical trials of A-101 in patients with SK. In addition to developing A-101 for the treatment of SK, we are also developing A-101 as a prescription treatment for common warts as well as A-102, a gel dosage form of hydrogen peroxide, as a prescription treatment for SK and common warts. Therefore, we expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- § continue our ongoing clinical trials evaluating A-101 for the treatment of SK;
- § pursue regulatory approvals for A-101 for the treatment of SK and for any other drug candidates that successfully complete clinical trials;
- § initiate clinical trials of our other drug candidates, including A-101 for the treatment of common warts and A-102 for the treatment of SK and common warts;
- § seek to discover and develop additional drug candidates;
- § ultimately establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any drug candidates for which we may obtain regulatory approval;
- § seek to in-license or acquire additional drug candidates for other dermatological conditions;
- § adapt our regulatory compliance efforts to incorporate requirements applicable to marketed drugs;
- § maintain, expand and protect our intellectual property portfolio;
- § hire additional clinical, manufacturing and scientific personnel;
- § add operational, financial and management information systems and personnel, including personnel to support our drug development and planned future commercialization efforts; and
- § incur additional legal, accounting and other expenses in operating as a public company.

To become and remain profitable, we must succeed in developing and eventually commercializing drug candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, obtaining regulatory approval, and manufacturing, marketing and selling any drug candidates for which we may obtain

regulatory approval, as well as discovering and developing additional drug candidates. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

In cases where we are successful in obtaining regulatory approval to market one or more of our drug candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such drug products, even if approved.

Because of the numerous risks and uncertainties associated with drug development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform studies in addition to those expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our drug candidates, our expenses could increase.

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

Even if this offering is successful, we will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Identifying potential drug candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we commence our Phase 3 clinical trials of A-101 in patients with SK, seek marketing approval for A-101 for the treatment of SK and advance our other drug candidates. In addition, our drug candidates, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of drugs that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for A-101 for the treatment of SK or any other drug candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company.

As of December 31, 2014, we had cash, cash equivalents and marketable securities of \$16.6 million. We believe that the anticipated net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months. This estimate is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we expect. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional drug candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- § the progress and results of the three Phase 3 clinical trials of A-101 in patients with SK that we plan to commence in the second half of 2015;

- § the progress and results of the toxicology studies and Phase 2 clinical trials evaluating A-101 as a potential treatment for common warts;
- § the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other drug candidates, including A-102;
- § the extent to which we in-license or acquire other drug candidates and technologies;
- § the number and development requirements of other drug candidates that we may pursue;
- § the costs, timing and outcome of regulatory review of our drug candidates;
- § the costs and timing of future commercialization activities, including drug manufacturing, marketing, sales and distribution, for any of our drug candidates for which we receive marketing approval;
- § the revenue, if any, received from commercial sales of our drug candidates for which we receive marketing approval;
- § our ability to establish collaborations to commercialize A-101 outside the United States; and
- § the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims.

We expect that we will require additional capital to commercialize A-101 for the treatment of SK. If we receive regulatory approval for A-101 for this indication, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Raising additional capital may cause dilution to our stockholders, including purchasers of common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or drug candidates.

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history and no history of commercializing drugs, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced operations in 2012, and our operations to date have been largely focused on raising capital and developing A-101 for the treatment of SK, including undertaking preclinical studies and conducting clinical trials. A-101 for the treatment of SK is our only drug candidate for which we have conducted clinical trials. We have not yet demonstrated our ability to successfully complete later-stage clinical trials, obtain regulatory approvals, manufacture a drug on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they

could be if we had a longer operating history or a history of successfully developing and commercializing drugs.

We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to transition at some point from a company with a development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Risks Related to the Development of Our Drug Candidates

We are early in our development efforts and have only one drug candidate, A-101 for the treatment of SK, for which we have conducted clinical trials. If we are unable to successfully develop, receive regulatory approval for and commercialize A-101 for the treatment of SK or any other drug candidates, or experience significant delays in doing so, our business will be harmed.

We currently have no drug products that are approved for commercial sale. We are early in our development efforts and have only one drug candidate, A-101 for the treatment of SK, for which we have conducted Phase 2 clinical trials. We have not completed the development of any drug candidates and we may never be able to develop marketable drugs. We have invested substantially all of our efforts and financial resources in the development of A-101 for the treatment of SK, the development of our other drug candidates and the identification of potential drug candidates. Our ability to generate revenue from our drug candidates, which we do not expect will occur for a number of years, if ever, will depend heavily on their successful development, regulatory approval and eventual commercialization of these drug candidates. The success of A-101 or any other drug candidates that we develop will depend on several factors, including:

- § successful completion of preclinical studies and our clinical trials;
- § successful development of our manufacturing processes for any of our drug candidates that receive regulatory approval;
- § receipt of timely marketing approvals from applicable regulatory authorities;
- § launching commercial sales of drugs, if approved;
- § acceptance of our drugs, if approved, by patients, the medical community and third-party payors, and willingness of patients to pay out of pocket for procedures using our drug candidates for the treatment of SK;
- § our success in educating physicians and patients about the benefits, administration and use of A-101 or any other drug candidates, if approved;
- § the prevalence and severity of adverse events experienced with A-101 or our other drug candidates;
- § the availability, perceived advantages, cost, safety and efficacy of alternative treatments for SK;
- § obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our drug candidates and otherwise protecting our rights in our intellectual property portfolio;
- § maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs;
- § competing effectively with other procedures; and
- § maintaining a continued acceptable safety, tolerability and efficacy profile of the drugs following approval.

Whether regulatory approval will be granted is unpredictable and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Our drug candidates' success in clinical trials will not guarantee regulatory approval. If, following submission, our NDA for A-101 for the treatment of SK or any other drug candidate is not accepted for substantive review, or even if it is accepted for substantive review, the FDA or other comparable foreign regulatory authorities may require that we conduct additional studies or clinical trials, provide additional data, take additional manufacturing steps, or require other conditions before they will reconsider or approve our application. If the FDA or other comparable foreign

regulatory authorities require additional studies, clinical trials or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA or other comparable foreign regulatory authorities may not consider sufficient any additional required studies, clinical trials, data or information that we perform and complete or generate, or we may decide to abandon the program.

It is possible that A-101 or any of our other drug candidates will never obtain regulatory approval, even if we expend substantial time and resources seeking such approval. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would harm our business.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

The risk of failure for our drug candidates is high. It is impossible to predict when or if any of our drug candidates will prove effective or safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We have not completed all clinical trials required for the approval of any of our drug candidates. Based on the feedback from our recent meeting with the FDA in May 2015, we plan to commence three Phase 3 clinical trials of A-101 in patients with SK lesions on the face, trunk and extremities in the second half of 2015. We have also requested scientific advice from the EMA for A-101 for the treatment of SK. The development of our other drug candidates is less advanced and we have not commenced any clinical trials. We cannot assure you that any Phase 3 or other clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our drug candidates.

We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our drug candidates, including:

- § regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- § we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- § clinical trials of our drug candidates may produce negative or inconclusive results, including failure to demonstrate statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- § the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- § our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials;

- § our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- § regulators or institutional review boards may require that we or our investigators suspend or terminate clinical development for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- § the cost of clinical trials of our drug candidates may be greater than we anticipate; and
- § the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the institutional review boards of the institutions in which such trials are being conducted, by the data safety monitoring board for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate product revenues from any of these drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not favorable or if there are safety concerns, we may:

- § be delayed in obtaining marketing approval for our drug candidates;
- § not obtain marketing approval at all;
- § obtain approval for indications or patient populations that are not as broad as intended or desired;
- § obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- § be subject to additional post-marketing testing requirements; or
- § have the drug removed from the market after obtaining marketing approval.

Our drug development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring drugs to market before we do and impair our ability to successfully commercialize our drug candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible

patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- § the eligibility criteria for the trial in question;
- § the perceived risks and benefits of the drug candidate in the trial;
- § the availability of drugs approved to treat the skin disease in the trial;
- § the efforts to facilitate timely enrollment in clinical trials;
- § the patient referral practices of physicians;
- § the ability to monitor patients adequately during and after treatment; and
- § the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us or them to abandon one or more clinical trials altogether. Enrollment delays in these clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Our clinical trials may fail to demonstrate the safety and efficacy of our drug candidates, or serious adverse or unacceptable side effects may be identified during the development of our drug candidates, which could prevent or delay regulatory approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our drug candidates.

Before obtaining regulatory approvals for the commercial sale of our drug candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our drug candidates are both safe and effective for use in each target indication, and failures can occur at any stage of testing. Clinical trials often fail to demonstrate safety and efficacy of the drug candidate studied for the target indication.

If our drug candidates are associated with side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The FDA or an institutional review board may also require that we suspend, discontinue, or limit our clinical trials based on safety information. Such findings could further result in regulatory authorities failing to provide marketing authorization for our drug candidates. Many drug candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the drug candidate.

Additionally, if one or more of our drug candidates receives marketing approval, and we or others identify undesirable side effects caused by such drugs, a number of potentially significant negative consequences could result, including:

- § regulatory authorities may withdraw approvals of such product;
- § regulatory authorities may require additional warnings on the labels;
- § we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- § we could be sued and held liable for harm caused to patients; and
- § our reputation and physician or patient acceptance of our products may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, if approved, and could significantly harm our business, results of operations and prospects.

Changes in methods of drug candidate manufacturing or formulation may result in additional costs or delay.

As drug candidates are developed through preclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our drug candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. For example, if we need to manufacture A-102, we may experience difficulties manufacturing a stable gel dosage form as opposed to a topical solution. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our drug candidates and jeopardize our ability to commence sales and generate revenue.

We may not be successful in our efforts to increase our pipeline of drug candidates, including by in-licensing or acquiring additional drug candidates for other dermatological conditions.

A key element of our strategy is to build and expand our pipeline of drug candidates. In addition, we intend to in-license or acquire additional drug candidates for other dermatological conditions to build a fully integrated dermatology company. We may not be able to identify or develop drug candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential drug candidates that we identify, in-license or acquire may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance.

We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we focus on development programs and drug candidates that we identify for specific indications. As such, we are currently primarily focused on the development of A-101 for the treatment of SK. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future development programs and drug candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

Risks Related to the Commercialization of Our Drug Candidates

Even if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our drug candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- § the efficacy, safety and potential advantages compared to alternative treatments;
- § our ability to offer our drugs for sale at competitive prices;

- § the ability of dermatologists to charge a premium for A-101 and our other drug candidates;
- § the convenience and ease of administration compared to alternative treatments;
- § the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- § our ability to hire and retain a sales force in the United States;
- § the strength of marketing and distribution support;
- § the willingness of patients to pay out of pocket for procedures using A-101 for the treatment of SK;
- § the availability of third-party coverage and adequate reimbursement;
- § the prevalence and severity of any side effects; and
- § any restrictions on the use of our drugs together with other medications.

If we are unable to establish sales, marketing and distribution capabilities for A-101 or any other drug candidate that may receive regulatory approval, we may not be successful in commercializing those drug candidates if and when they are approved.

We have never commercialized a drug candidate and we do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical drugs. To achieve commercial success for A-101 and any other drug candidate for which we may obtain marketing approval, we will need to establish a sales and marketing organization. In the future, we expect to build a focused sales and marketing infrastructure to market or co-promote some of our drug candidates in the United States, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any drug launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

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

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

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

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 and specialty pharmaceutical companies, academic institutions and governmental agencies and public and private research institutions.

With respect to A-101 for the treatment of SK, we are aware of one biopharmaceutical company developing a combination drug candidate that targets SK, and another company that currently markets a line of cosmetic products targeting skin conditions, including SK.

With respect to A-101 for the treatment of common warts, we are aware of one company developing a prescription treatment for common warts and another company that intends to initiate a Phase 2 clinical trial of a gel as a prescription treatment for 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 A-101 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.

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 testing, conducting clinical trials, 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.

We expect third-party payors generally will not cover the use of our drug candidates for the treatment of SK and, accordingly, our success will be dependent upon the willingness of patients to pay out of pocket for procedures using these drug candidates.

We do not expect third-party payors to cover and reimburse providers who use A-101 or A-102 on patients for the treatment of SK. Payors generally do not reimburse the provider for the product used to remove non-malignant lesions, including SK. In addition, they do not generally reimburse providers for the procedure removing such lesions, since the procedure is considered to be cosmetic in nature, unless there is a medical need to remove the lesion such as confirming a diagnosis with a biopsy or treating SK that are causing the patient physical discomfort. We anticipate that in some cases, our drug candidates will be used to remove SK lesions that are inflamed and causing the patient discomfort. Any reduction in reimbursement for the procedure to remove inflamed SK may result in a higher percentage of patients needing to pay out of pocket for treatment with our drug candidates. Accordingly, the commercial success of A-101 and A-102 depends on the extent to which patients will be willing to pay out of pocket for the in-office procedure using these drug candidates.

The success of our drug candidates for the treatment of common warts will depend significantly on continued coverage and adequate reimbursement or the willingness of patients to pay for these procedures.

In the case of A-101 and A-102 for the treatment of common warts, we believe our success depends on continued coverage and adequate reimbursement for in-office wart treatment procedures or, in the absence of coverage and adequate reimbursement, on the extent to which patients will be willing to pay out of pocket for the in-office procedures that include our drug candidates.

Third-party payors determine which medical procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure and may be unwilling to undergo such procedures for the removal of warts in the absence of such coverage and reimbursement. Physicians may be unlikely to offer procedures for the treatment of warts if they are not covered by insurance and may be unlikely to purchase and use our product for warts unless coverage is provided and reimbursement is adequate.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is neither cosmetic, experimental, nor investigational; safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; and included in clinical practice guidelines.

Further, from time to time, typically on an annual basis, payment amounts are updated and revised by third-party payors. To the extent that the procedures using our drug candidates, if approved, are covered, the cost of our products are generally recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed. Accordingly, these updates could impact the demand for our drug candidates, if approved. An example of payment updates is the Medicare program updates to physician payments, which is done on an annual basis using a prescribed statutory formula. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. Most recently, the Protecting Access to Medicare Act of 2014, signed into law in April 2014, provided for a 0.5% update from 2013 payment rates under the Medicare Physician Fee Schedule through 2014 and a 0% update from January 1 until March 31, 2015. If Congress fails to intervene to prevent the negative update factor in future years, the resulting decrease in payment may adversely affect our revenue and results of operations. In addition, the Medicare physician fee schedule has been adapted by some private payors into their plan-specific physician payment schedule. We cannot predict how pending and future healthcare legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our drug candidates or lowers reimbursement for procedures using our products could harm our business.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our drugs are used under any foreign reimbursement system.

There can be no assurance that our drug candidates for the treatment of common warts, if they are approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our drugs candidates profitably if they are approved for sale.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any drugs that we may develop.

We face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and will face an even greater risk if we commercially sell any drugs that we may develop. If we cannot successfully defend ourselves against claims that our drug candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- § decreased demand for any drug candidates or drugs that we may develop;
- § injury to our reputation and significant negative media attention;
- § withdrawal of clinical trial participants;

- § significant costs to defend the related litigation;
- § substantial monetary awards paid to trial participants or patients;
- § loss of revenue;
- § reduced resources of our management to pursue our business strategy; and
- § the inability to commercialize any drugs that we may develop.

We currently hold \$5.0 million in product liability insurance coverage in the aggregate, with a per incident limit of \$5.0 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our drug candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our drug candidates could be delayed.

Risks Related to Our Dependence on Third Parties

We expect to rely on third parties to conduct our future clinical trials for drug candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We expect to engage a CRO to conduct our planned clinical trials of A-101 or any of our other drug candidates that may progress to clinical development. We expect to continue to rely on third parties, such as clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. Consequently, our results of operations and the commercial prospects for our drug candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to

carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

We contract with third parties for the manufacture of A-101 for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of A-101 or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of A-101 for preclinical and clinical testing, as well as for commercial manufacture if any of our drug candidates, including A-101, receive marketing approval. For example, we have entered into an exclusive, ten-year, automatically renewable supply agreement with PeroxyChem LLC, or PeroxyChem, a manufacturer of hydrogen peroxide, to provide the active pharmaceutical ingredient that can be used in A-101 for the treatment of SK. This reliance on third parties increases the risk that we will not have sufficient quantities of A-101 or such quantities at an acceptable cost or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development or commercialization efforts.

We also expect to rely on third-party manufacturers or third-party collaborators for the manufacture of commercial supply of A-101 or any other drug candidates for which we obtain marketing approval. The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable marketing application to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA

or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

We may be unable to establish any agreements with future third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- § reliance on the third party for regulatory compliance and quality assurance;
- § the possible breach of the manufacturing agreement by the third party;
- § the possible misappropriation of our proprietary information, including our trade secrets and know-how;
- § the possible increase in costs by PeroxyChem for the active pharmaceutical ingredient in A-101; and
- § the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs.

Our drug candidates and any drugs that we may develop may compete with other drug candidates and drugs for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. Our current and anticipated future dependence upon others for the manufacture of our drug candidates or drugs may adversely affect our future profit margins and our ability to commercialize any drugs that receive marketing approval on a timely and competitive basis.

We may seek collaborations with third parties for the development or commercialization of our drug candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these drug candidates.

We may seek third-party collaborators for the development and commercialization of our drug candidates, including for the commercialization of any of our drug candidates that are approved for marketing outside the United States. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we do enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our drug candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our drug candidates would pose the following risks to us:

- § collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- § collaborators may not perform their obligations as expected;

- § collaborators may not pursue development and commercialization of any drug candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- § collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a drug candidate, repeat or conduct new clinical trials or require a new formulation of a drug candidate for clinical testing;
- § collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our drug candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- § drug candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own drug candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our drug candidates;
- § a collaborator with marketing and distribution rights to one or more of our drug candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such drugs;
- § disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of drug candidates, might lead to additional responsibilities for us with respect to drug candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- § collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- § collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- § collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable drug candidates.

Collaboration agreements may not lead to development or commercialization of drug candidates in the most efficient manner or at all. If a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our drug candidates will require substantial additional capital. For some of our drug candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without

regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative drug candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our drug candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such drug candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate revenue.

Risks Related to Our Intellectual Property

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 prosecution of patent applications, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be 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 United States 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 were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we 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 United States 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 is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Even if our owned and licensed patent applications 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 owned or licensed patents by developing similar or alternative technologies or drugs in a non-infringing manner.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed 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. 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 owned and licensed 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.

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. In addition, in a patent infringement proceeding, a court 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 litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly.

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 A-101 for the treatment of SK is covered in the United States, Australia, India and New Zealand, but not Europe. 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.

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development of our drug candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our drug candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our drugs and technology, including interference or derivation proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our drug candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our drugs and technology. However, we

may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or drug. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing product or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

If we were to initiate legal proceedings against a third party to enforce a patent directed at our drug candidates, or one of our future drug candidates, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. 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, 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.

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.

Most of our competitors are larger than we are and have substantially greater resources. They are, therefore, likely to be able to sustain the costs of complex patent litigation longer than we could. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation could result in substantial costs and diversion of management resources, which could harm our business. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or in-license needed technology or other drug candidates. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us commercialize our drug candidates, if approved.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our drug candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position.

We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our

trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

The validity, scope and enforceability of any patents listed in the Orange Book that cover A-101 can be challenged by competitors.

If A-101 is approved by the FDA, one or more third parties may challenge the patents covering A-101, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug containing A-101, 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. 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 our drug candidates.

If we do not obtain protection under the Hatch-Waxman Amendments by extending the patent term and obtaining data exclusivity for our drug candidates, our business may be materially harmed.

Our commercial success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, drug candidates and our target indications. Our issued U.S. patents, with claims directed to treatment of SK and acrochordons, are set to expire in 2022. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting our drug candidates might expire before or shortly after such candidates begin to be commercialized. We expect to seek extensions of patent terms in the U.S. and, if available, in other countries where we are prosecuting patents.

Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. We also intend to pursue additional patent

protection for our drug candidates that, if issued, would naturally expire in 2035 or later. However, we may not obtain such patent protection.

If we are unable to extend the expiration date of our existing patents or obtain new patents with longer expiry dates, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and pre clinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case.

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our drug candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

Outside of the United States we cannot be certain that any country's patent or trademark office will not implement new rules that could seriously affect how we draft, file, prosecute and maintain patents, trademarks and patent and trademark applications.

We cannot be certain that the patent or trademark offices of countries outside the United States will not implement new rules that increase costs for drafting, filing, prosecuting and maintaining patents, trademarks and patent and trademark applications or that any such new rules will not restrict our ability to file for patent protection. For example, we may elect not to seek patent protection in some jurisdictions or for some drug candidates in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- § others may be able to make formulations or compositions that are the same as or similar to A-101 but that are not covered by the claims of the patents that we own;
- § we or any collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- § we might not have been the first to file patent applications covering certain of our inventions;
- § others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- § it is possible that our pending patent applications will not lead to issued patents;
- § issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- § our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and
- § we may not develop additional proprietary technologies that are patentable.

Risks Related to Regulatory Approval of Our Drug Candidates and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals, we will not be able to commercialize our drug candidates, and our ability to generate revenue will be materially impaired.

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for a drug candidate will prevent us from commercializing the drug candidate. We have not received approval to market any of our drug candidates from regulatory authorities in any jurisdiction. We have only limited experience in filing and supporting the applications necessary to gain marketing approvals. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Our drug candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug in this way, which could limit sales of the drug.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the drug candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted drug application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a drug candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our drug candidates, the commercial prospects for our drug candidates may be harmed and our ability to generate revenue will be materially impaired.

Failure to obtain marketing approval in international jurisdictions would prevent our drug candidates from being marketed abroad.

In order to market and sell our drugs in the European Union and any other jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. We may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, failure to obtain approval in one jurisdiction may impact our ability to obtain approval elsewhere. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our drugs in any market.

A variety of risks associated with marketing our drug candidates internationally could harm our business.

We may seek regulatory approval for A-101 and our other drug candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- § differing regulatory requirements in foreign countries;
- § the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- § unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- § economic weakness, including inflation, or political instability in particular foreign economies and markets;
- § foreign reimbursement, pricing and insurance regimes;
- § compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- § foreign taxes, including withholding of payroll taxes;
- § foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- § difficulties staffing and managing foreign operations;
- § workforce uncertainty in countries where labor unrest is more common than in the United States;
- § potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- § challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- § production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- § business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may compromise our ability to achieve or maintain profitability.

Any drug candidate for which we obtain marketing approval could be subject to post-marketing restrictions or recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our drug candidates, when and if any of them are approved.

Any drug candidate for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for such drug candidate, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a drug candidate is granted, the approval may be subject to limitations on the indicated uses for which the drug candidate may be marketed or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy. If any of our drug candidates receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the drug. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with

the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our drugs for their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have negative consequences, including:

- § restrictions on such drugs, manufacturers or manufacturing processes;
- § restrictions on the labeling or marketing of a drug;
- § restrictions on drug distribution or use;
- § requirements to conduct post-marketing studies or clinical trials;
- § warning letters;
- § recall or withdrawal of the drugs from the market;
- § refusal to approve pending applications or supplements to approved applications that we submit;
- § clinical holds;
- § fines, restitution or disgorgement of profits or revenue;
- § suspension or withdrawal of marketing approvals;
- § refusal to permit the import or export of our drugs;
- § drug seizure; or
- § injunctions or the imposition of civil or criminal penalties.

Non-compliance with the European Union's requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of drugs for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Our current and future relationships with third-party payors, health care professionals and customers in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to significant penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our future arrangements with third-party payors, health care professionals and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we sell, market and distribute any drugs for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include the following:

- § the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- § federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or *qui tam* actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- § the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- § HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- § the federal Open Payments program, created under Section 6002 of Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other "transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers to report annually to CMS ownership and investment interests held by the physicians and their immediate family members by the 90th day of each calendar year. All such reported information is publicly available; and
- § analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase and/or prescribe our drug candidates, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. By way of example, some of our consulting arrangements with physicians may not meet all of the criteria of the personal services safe harbor under the federal Anti-Kickback Statute. Accordingly, they may not qualify for safe harbor protection from government prosecution. A business arrangement that does not substantially comply with a safe harbor, however, is not necessarily illegal under the Anti-Kickback Statute, but may be subject to additional scrutiny by the government.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act of importance to our potential drug candidates are the following:

- § an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- § an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- § expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, which include new government investigative powers and enhanced penalties for non-compliance;
- § a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- § extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- § expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, thereby potentially increasing manufacturers' Medicaid rebate liability;
- § expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- § the new requirements under the federal Open Payments program and its implementing regulations;
- § a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and

- § a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year effective April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2024 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

We expect that the Affordable Care Act, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs.

Additionally, new litigation challenging the federal tax subsidies received by individuals to purchase health insurance under the Affordable Care Act is currently pending before the U.S. Supreme Court that could affect our business. Final regulations, guidance, and judicial orders are anticipated in the near future and we will continue to assess the Affordable Care Act's impact on us as final regulations, guidance, and orders are issued.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our drug candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent drug labeling and post-marketing testing and other requirements.

We may not be able to obtain five-year FDA regulatory exclusivity as an NCE.

The FDA provides periods of regulatory exclusivity following their approval of an NDA, which provide the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug. Five-year exclusivity precludes approval of 505(b)(2) applications or ANDAs by delaying the submission or approval of such applications, while three-year exclusivity precludes the approval of such applications. We intend to seek new chemical entity, or NCE, status for A-101, and we may seek NCE status for other drug candidates as appropriate. Five years of exclusivity are available to NCEs following the approval of an NDA by the FDA. An NCE is a drug that contains no active moiety that has been approved by FDA in any other NDA. If a drug is not eligible for the NCE exclusivity, it may be eligible for three years of exclusivity. Three-year exclusivity is available to the holder of an NDA for a particular condition of approval, or change to a marketed product, such as a new formulation for a previously approved product, if one or more new clinical trials, other than bioavailability or bioequivalence trials, were essential to the approval of the application and were conducted or sponsored by the applicant.

There is a risk that the FDA may disagree with any claim that we may make that A-101 or any of our other drug candidates are NCEs and therefore entitled to five-year exclusivity.

If we do obtain either five or three years of exclusivity, such exclusivity will not block all potential competitors from the market. Five-year exclusivity does not block complete 505(b)(1) NDAs and the scope of three-year exclusivity is limited to the conditions for use approved in the NDA.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our drug candidate to other available procedures. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

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

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

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

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

The inherent dangers in production and transportation of hydrogen peroxide could cause disruptions and could expose us to potentially significant losses, costs or liabilities.

Our operations are subject to significant hazards and risks inherent in the use and transport of hydrogen peroxide, the active ingredient of A-101 and A-102. Hydrogen peroxide can decompose in the presence of organic materials and is categorized as an oxidizer and is corrosive. Hydrogen peroxide should be stored in cool, dry, well-ventilated areas and away from any flammable or combustible substances. The hazards and risks associated with producing and transporting hydrogen peroxide include fires, explosions, third-party interference (including terrorism) and mechanical failure of equipment at our facilities or those of our supplier of hydrogen peroxide. The occurrence of any of these events could result in production and distribution difficulties and disruptions, personal injury or wrongful death claims and other damage to properties.

We are subject to governmental economic sanctions and export and import controls that could impair our ability to compete in international markets or subject us to liability if we are not in compliance with applicable laws.

As a U.S. company, we are subject to U.S. import and export controls and economic sanctions laws and regulations, and we are required to import and export our drug candidates, technology and services in compliance with those laws and regulations, including the U.S. Export Administration Regulations, the International Traffic in Arms Regulations, and economic embargo and trade sanction programs administered by the Treasury Department's Office of Foreign Assets Control.

U.S. economic sanctions and export control laws and regulations prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. While we are currently taking precautions to prevent doing any business, directly or indirectly, with countries, governments and persons targeted by U.S. sanctions and to ensure that our drug candidates, if approved, are not exported or used by countries, governments and persons targeted by U.S. sanctions, such measures may be circumvented.

Furthermore, if we export our drug candidates, if approved, the exports may require authorizations, including a license, a license exception or other appropriate government authorization. Complying with export control and sanctions regulations for a particular sale may be time-consuming and may result in the delay or loss of sales opportunities. Failure to comply with export control and sanctions regulations for a particular sale may expose us to government investigations and penalties.

If we are found to be in violation of U.S. sanctions or import or export control laws, it could result in civil and criminal, monetary and non-monetary penalties, including possible incarceration for those individuals responsible for the violations, the loss of export or import privileges and reputational harm.

We are subject to anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and possibly other anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. As we commercialize our drug candidates and eventually commence international sales and business, we may engage with collaborators and third-party intermediaries to sell our products abroad and to obtain necessary permits, licenses and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. Responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

Risks Related to Employee Matters and Managing Our Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, development, clinical, financial and business development expertise of Dr. Neal Walker, our Chief Executive Officer, Christopher Powala, our Chief Operating Officer, Dr. Stuart Shanler, our Chief Scientific Officer, Frank Ruffo, our Chief Financial Officer, and Kamil Ali-Jackson, our Chief Legal Officer, as well as the other members of our scientific and clinical teams. Although we intend to enter into new employment agreements with our executive officers that will be effective upon the closing of this offering, each of them may currently terminate their employment with us at any time and will continue to be able to do so after the closing of this offering. We do not maintain "key person" insurance for any of our executives or employees other than Dr. Walker and Mr. Powala.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our drug pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of March 31, 2015, we had ten full-time employees. As our development progresses, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs and, if any of our drug candidates receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, prospective CROs and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, prospective CROs and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates FDA regulations, including those laws

requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Effective upon the closing of this offering, we will adopt a code of business conduct and ethics, but it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Risks Related to this Offering, Ownership of Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at or above the initial offering price, if at all.

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock will be determined through negotiations with the underwriters and may not be indicative of the price at which our common stock will trade after the closing of this offering. Although we intend to apply to list our common stock on The NASDAQ Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased in this offering at an attractive price or at all.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- § the commencement, enrollment or results of the planned clinical trials of A-101 in patients with SK or any future clinical trials we may conduct, or changes in the development status of our drug candidates;
- § any delay in our regulatory filings for A-101 for the treatment of SK or any other drug candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- § adverse results from, delays in or termination of clinical trials;
- § adverse regulatory decisions, including failure to receive regulatory approval of our drug candidates;
- § unanticipated serious safety concerns related to the use of A-101 or any other drug candidate;
- § changes in financial estimates by us or by any securities analysts who might cover our stock;
- § conditions or trends in our industry;
- § changes in the market valuations of similar companies;

- § stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- § publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- § announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- § announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- § investors' general perception of our company and our business;
- § recruitment or departure of key personnel;
- § overall performance of the equity markets;
- § trading volume of our common stock;
- § disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- § significant lawsuits, including patent or stockholder litigation;
- § general political and economic conditions; and
- § other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock after this offering, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

If you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.

We expect the initial public offering price of our common stock to be substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on an assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of \$ _____ per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the assumed initial public offering price.

In addition, as of January 31, 2015, we had outstanding stock options to purchase an aggregate of 1,725,961 shares of common stock at a weighted average exercise price of \$0.35 per share. To the extent these outstanding options are exercised, there will be further dilution to investors in this offering.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market following this offering, the market price of our common stock could decline significantly.

Upon the closing of this offering, we will have outstanding _____ shares of common stock, after giving effect to the conversion of our redeemable convertible preferred stock outstanding as of January 31, 2015 into 27,341,057 shares of our common stock, and assuming no exercise of outstanding options. Of these shares, the _____ shares sold in this offering and _____ additional shares will be freely tradable, _____ additional shares of common stock will be eligible for sale in the public market beginning 90 days after the date of this prospectus, subject to volume, manner of sale and other limitations of Rule 144 and Rule 701, and _____ additional shares of common stock will be available for sale in the public market beginning 180 days after the date of this prospectus following the expiration of lock-up agreements between some of our stockholders and the underwriters. The representatives of the underwriters may release these stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market.

In addition, promptly following the closing of this offering, we intend to file one or more registration statements on Form S-8 registering the issuance of approximately _____ shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Additionally, after this offering, the holders of an aggregate of _____ shares of our common stock, or their transferees, will have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws as they will be in effect following this offering that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to _____ shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, including:

- § only one of our three classes of directors will be elected each year;
- § stockholders will not be entitled to remove directors other than by a 66²/3% vote and only for cause;
- § stockholders will not be permitted to take actions by written consent;
- § stockholders cannot call a special meeting of stockholders; and

§ stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Upon the closing of this offering, our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates will, in the aggregate, beneficially own approximately % of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We are an "emerging growth company" and, as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- § being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- § not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- § not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- § reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- § not being required to hold a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenue of at least \$1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock

that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

After the closing of this offering, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Commencing with our fiscal year ending December 31, 2016, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act. This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. Prior to this offering, we have never been required to test our internal control within a specified period, and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission, or SEC, or other regulatory authorities.

We will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

We will have broad discretion over the use of proceeds from this offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We expect to use the net proceeds to us from this offering, together with our existing cash, cash equivalents and marketable securities, to complete our planned clinical trials and seek regulatory approval of A-101 for the treatment of SK, to fund continued research and development of A-101 for the treatment of common warts and A-102 gel dosage form for the treatment of SK and common warts, and for working capital and general corporate purposes. In addition, we may use a portion of the proceeds from this offering to pursue our strategy to in-license or acquire additional drug candidates. Our failure to apply the net proceeds from this offering effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

We might not be able to utilize a significant portion of our net operating loss carryforwards and research and development tax credit carryforwards.

As of December 31, 2014, we had federal and state net operating loss carryforwards of \$13.8 million and \$13.8 million, respectively, and federal research and development tax credit carryforwards of \$0.2 million, each of which if not utilized will begin to expire in 2032. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our net operating loss and tax credit carryforwards are subject to an annual limitation under Section 382. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including this offering, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, the terms of any existing or future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

We will incur increased costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we will incur significant additional legal, accounting and other costs, which we anticipate could be between \$1.0 million and \$2.0 million annually. These additional costs could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The NASDAQ Stock Market, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business," but are also contained elsewhere in this prospectus. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and important factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- § our plans to develop and commercialize our drug candidates;
- § the timing of our planned clinical trials of A-101 in patients with SK and our other drug candidates;
- § the timing of our NDA filing for A-101 for the treatment of SK;
- § the timing of and our ability to obtain and maintain regulatory approvals for our drug candidates;
- § the clinical utility of our drug candidates;
- § our commercialization, marketing and manufacturing capabilities and strategy;
- § our expectations about the willingness of patients to pay out of pocket for procedures using our drug candidates for the treatment of SK;
- § our expectations about the willingness of dermatologists to use A-101 for the treatment of SK;
- § our intellectual property position;
- § our plans to in-license or acquire additional drug candidates for other dermatological conditions to build a fully integrated dermatology company; and
- § our estimates regarding future revenue, expenses and needs for additional financing.

You should refer to the "Risk Factors" section of this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

INDUSTRY AND MARKET DATA

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties, as well estimates by our management based on such data. All of the market data and estimates used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data and estimates. We believe that the information from these industry publications, surveys and studies is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of important factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

USE OF PROCEEDS

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

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share would increase or decrease the net proceeds to us from this offering by \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the net proceeds to us from this offering by \$ _____ million, assuming no change in the assumed initial public offering price and after deducting the estimated underwriting discounts and commissions.

We currently estimate that we will use the net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, as follows:

- § approximately \$ _____ million to complete our three planned Phase 3 clinical trials and seek regulatory approval of A-101 for the treatment of SK;
- § approximately \$ _____ million to fund continued research and development of A-101 for the treatment of common warts, including the completion of our planned Phase 2 clinical trials for this indication; and
- § the remainder to fund other research and development activities, including the development of A-102 for the treatment of SK and common warts, as well as for working capital and other general corporate purposes, including to pursue our strategy to in-license or acquire additional drug candidates, although we have no agreements or commitments for any specific acquisitions or in-licenses as of the date of this prospectus.

This expected use of net proceeds from this offering and our existing cash, cash equivalents and marketable securities represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, as well as any collaborations that we may enter into with third parties for our drug candidates, and any unforeseen cash needs.

As a result, our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending these uses, we plan to invest these net proceeds in short-term, interest bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States.

We believe that the net proceeds from this offering will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least the next _____ months, including the completion of our three planned Phase 3 clinical trials for A-101 for the treatment of SK, the submission of our NDA to the FDA for the approval of A-101 for the treatment of SK in the United States and the completion of our planned Phase 2 clinical trials of A-101 for the treatment of common warts. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

DIVIDEND POLICY

We have never declared or paid any dividends on our common stock. We anticipate that we will retain all of our future earnings, if any, for use in the operation and expansion of our business and do not anticipate paying cash dividends in the foreseeable future.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and marketable securities and our capitalization as of December 31, 2014:

- § on an actual basis;
- § on a pro forma basis to give effect to:
 - § the conversion of all outstanding shares of our redeemable convertible preferred stock into an aggregate of 27,341,057 shares of our common stock, which will occur upon the closing of this offering; and
 - § the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- § on a pro forma as adjusted basis to give further effect to our sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Our capitalization following the closing of this offering will depend on the actual initial public offering price and other terms of this offering determined at pricing. You should read this information in conjunction with our financial statements and the related notes thereto included elsewhere in this prospectus and the sections of this prospectus titled "Selected Financial Data," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Description of Capital Stock."

	As of December 31, 2014		
	Actual	Pro Forma	Pro Forma As Adjusted
	(in thousands, except share data)		
Cash, cash equivalents and marketable securities	\$ 16,648	\$ 16,648	\$
Redeemable convertible preferred stock (Series A and B), \$0.00001 par value; 34,090,000 shares authorized, 27,341,057 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	\$ 36,677	\$ —	\$
Stockholders' equity (deficit):			
Preferred stock, \$0.00001 par value; no shares authorized, issued or outstanding, actual; _____ shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	
Common stock, \$0.00001 par value; 77,000,000 shares authorized, 9,420,000 shares issued and outstanding, actual; _____ shares authorized, 36,761,057 shares issued and outstanding, pro forma; _____ shares authorized, _____ shares issued and outstanding, pro forma as adjusted	—	—	
Additional paid-in capital	—	36,677	
Accumulated other comprehensive loss	(6)	(6)	
Accumulated deficit	(20,749)	(20,749)	
Total stockholders' equity (deficit)	(20,755)	15,922	
Total capitalization	\$ 15,922	\$ 15,922	\$

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity and total capitalization by \$ _____ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. Each increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the pro forma as adjusted amount of each of cash, cash equivalents and marketable securities, additional paid-in capital, total stockholders' equity and total capitalization by \$ _____ million, assuming no change in the assumed initial public offering price per share.

The number of shares of common stock outstanding in the table above does not include:

- § 1,725,961 shares of our common stock issuable upon the exercise of stock options outstanding under our 2012 equity compensation plan as of December 31, 2014, at a weighted average exercise price of \$0.35 per share; and
- § _____ shares of our common stock reserved for future issuance under our 2015 equity incentive plan, which will become effective upon the closing of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

DILUTION

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

Our historical net tangible book value (deficit) as of December 31, 2014 was \$(20.8) million, or \$(2.20) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and redeemable convertible preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the 9,420,000 shares of our common stock outstanding as of December 31, 2014.

Our pro forma net tangible book value as of December 31, 2014 was \$15.9 million, or \$0.43 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the conversion of all shares of our redeemable convertible preferred stock outstanding as of December 31, 2014 into an aggregate of 27,341,057 shares of our common stock, which will occur upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of December 31, 2014, after giving effect to the conversion of all shares of our redeemable convertible preferred stock outstanding as of December 31, 2014 into an aggregate of 27,341,057 shares of our common stock, which will occur upon the closing of this offering.

After giving further effect to our sale of _____ shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2014 would have been \$ _____ million, or \$ _____ per share. This represents an immediate increase in pro forma as adjusted net tangible book value of \$ _____ per share to existing stockholders and an immediate dilution in pro forma net tangible book value of \$ _____ per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share	\$ _____
Historical net tangible book value (deficit) per share as of December 31, 2014	\$ (2.20)
Increase per share attributable to the conversion of all outstanding shares of redeemable convertible preferred stock	<u>2.63</u>
Pro forma net tangible book value per share as of December 31, 2014	0.43
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering	<u>_____</u>
Pro forma as adjusted net tangible book value per share after this offering	_____
Dilution per share to new investors purchasing shares in this offering	<u><u>\$ _____</u></u>

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share would increase or decrease our pro forma as adjusted net tangible book value by \$ _____ million, our pro forma as adjusted net tangible book value per share after this offering by \$ _____ and dilution per share to new

investors purchasing shares in this offering by \$ _____, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. An increase of 1.0 million in the number of shares we are offering would increase the pro forma as adjusted net tangible book value per share after this offering by \$ _____ and decrease the dilution per share to new investors participating in this offering by \$ _____, assuming no change in the assumed initial public offering price per share and after deducting the estimated underwriting discounts and commissions. A decrease of 1.0 million in the number of shares we are offering would decrease the pro forma as adjusted net tangible book value per share after this offering by \$ _____ and increase the dilution per share to new investors participating in this offering by \$ _____, assuming no change in the assumed initial public offering price per share and after deducting the estimated underwriting discounts and commissions.

If the underwriters exercise their option to purchase _____ additional shares in full, our pro forma as adjusted net tangible book value per share after this offering would be \$ _____ per share, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$ _____ to existing stockholders and immediate dilution of \$ _____ in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering, assuming an initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

The following table summarizes, on the pro forma as adjusted basis described above, the number of shares of our common stock, the total consideration and the average price per share (i) paid to us by existing stockholders and (ii) to be paid by investors purchasing shares of common stock in this offering at an assumed initial public offering price of \$ _____ per share, which is the midpoint of the price range set forth on the cover page on this prospectus, before deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders			__\$		__\$
New investors					\$
Total		100.0%	\$	100.0%	

Each \$1.00 increase or decrease in the assumed initial public offering price of \$ _____ per share would increase or decrease the total consideration paid by new investors by \$ _____ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by _____ percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by _____ percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the total consideration paid by new investors by \$ _____ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by _____ percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by _____ percentage points, assuming no change in the assumed initial public offering price per share.

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to _____ % of the total number of shares

of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to % of the total number of shares of our common stock outstanding after this offering.

The tables and discussion above do not include:

- § 1,725,961 shares of our common stock issuable upon the exercise of stock options outstanding under our 2012 equity compensation plan as of December 31, 2014, at a weighted average exercise price of \$0.35 per share; and
- § shares of our common stock reserved for future issuance under our 2015 equity incentive plan, which will become effective upon the closing of this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under this plan.

To the extent that stock options are exercised, new stock options are issued under our equity incentive plan, or we issue additional shares of common stock in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and the related notes thereto included elsewhere in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. We have derived the statement of operations data for the years ended December 31, 2013 and 2014 and the balance sheet data as of December 31, 2013 and 2014 from our audited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future.

	Year Ended December 31,	
	2013	2014
	(in thousands, except per share data)	
Statement of Operations Data:		
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	3,488	6,507
General and administrative	1,769	2,026
Total operating expenses	5,257	8,533
Loss from operations	(5,257)	(8,533)
Interest income	21	16
Net loss	(5,236)	(8,517)
Accretion of redeemable convertible preferred stock to redemption value	(1,740)	(2,054)
Net loss attributable to common stockholders	\$ (6,976)	\$ (10,571)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.87)	\$ (1.78)
Weighted average common shares outstanding, basic and diluted	3,731	5,934
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		\$ (0.30)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)		28,468

	As of December 31,	
	2013	2014
	(in thousands)	
Balance Sheet Data:		
Cash, cash equivalents and marketable securities	\$ 14,126	\$ 16,648
Working capital	13,019	14,883
Total assets	14,207	17,377
Redeemable convertible preferred stock	23,000	36,677
Total stockholders' deficit	(9,163)	(20,755)

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Overview

We are a clinical-stage specialty pharmaceutical company focused on identifying, developing and commercializing innovative and differentiated topical drugs to address significant unmet needs in dermatology. Our lead drug candidate, A-101, is a proprietary high-concentration hydrogen peroxide topical solution that we are developing as a prescription treatment for seborrheic keratosis, or SK, a common non-malignant skin tumor. We have completed three Phase 2 clinical trials of A-101 in over 300 patients with SK. In these trials, following one or two applications of A-101, we observed clinically relevant and statistically significant improvements in clearing SK lesions on the face, trunk and extremities of the body. We plan to commence three Phase 3 clinical trials of A-101 in patients with SK in the second half of 2015 and, if the results of these trials are favorable, to submit a New Drug Application, or NDA, for A-101 for the treatment of SK to the U.S. Food and Drug Administration, or FDA, in the first half of 2016. We also intend to develop A-101 as a prescription treatment for common warts and A-102, a proprietary gel dosage form of hydrogen peroxide, as a prescription treatment for SK and common warts. In addition, we intend to in-license or acquire additional drug candidates for other dermatological conditions to build a fully integrated dermatology company.

Since our inception in July 2012, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, developing A-101 for the treatment of SK, building our intellectual property portfolio, developing our supply chain and engaging in other discovery and clinical activities in dermatology. To date, we have not generated any revenue and have financed our operations with \$31.5 million of gross proceeds from sales of our redeemable convertible preferred stock. We do not expect to generate significant revenue unless and until we obtain marketing approval for and commercialize A-101 for the treatment of SK or one of our other future drug candidates.

Since our inception, we have incurred significant operating losses. Our net loss was \$5.2 million for the year ended December 31, 2013 and \$8.5 million for the year ended December 31, 2014. As of December 31, 2014, we had an accumulated deficit of \$20.7 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical development and clinical trials, and seek regulatory approval and pursue commercialization of any approved drug candidate. In addition, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we may incur expenses in connection with the in-license or acquisition of additional drug candidates. Furthermore, upon the closing of this offering, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. We may be unable to

raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our drug candidates or delay our pursuit of potential in-licenses or acquisitions.

As of December 31, 2014, we had cash, cash equivalents and marketable securities of \$16.6 million. We believe that the anticipated net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. See "— Liquidity and Capital Resources."

Third-Party Agreements

Under an assignment agreement, pursuant to which we acquired intellectual property, we have agreed to pay royalties on sales of A-101 or related products at rates ranging in low single-digit percentages of net sales, as defined in the agreement. Under this assignment agreement, we have paid aggregate milestone payments of \$0.2 million and there are no remaining milestone payment obligations under this agreement.

In connection with this acquisition of intellectual property, we also entered into a finder's services agreement under which we have paid aggregate milestone payments of \$0.2 million and have agreed to make aggregate payments of up to \$1.3 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals, as described in the agreement. We have also agreed to make aggregate payments of up to \$4.5 million upon the achievement of specified commercial milestones. In addition, we have agreed to pay royalties on sales of A-101 or related products at a low single-digit percentage of net sales, as defined in the agreement.

Components of Our Results of Operations

Revenue

We have not generated any revenue since our inception and do not expect to generate any revenue from the sale of products in the near future.

Research and Development Expenses

Research and development expense consists of expenses incurred in connection with the discovery and development of our drug candidates. We expense research and development costs as incurred. These expenses include:

- § expenses incurred under agreements with contract research organizations, or CROs, as well as investigative sites and consultants that conduct our clinical trials and preclinical studies;
- § manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical and clinical trial materials and commercial materials, including manufacturing validation batches;
- § outsourced professional scientific development services;
- § employee-related expenses, which include salaries, benefits and stock-based compensation;
- § payments made under a third-party assignment agreement, under which we acquired intellectual property;
- § expenses relating to regulatory activities, including filing fees paid to regulatory agencies;
- § laboratory materials and supplies used to support our research activities; and
- § allocated expenses for utilities and other facility-related costs.

Research and development activities are central to our business model. Drug candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase

personnel costs, including stock-based compensation, commence Phase 3 clinical trials of A-101 in patients with SK and conduct other clinical trials and prepare regulatory filings for our drug candidates.

The successful development of our drug candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of, or when, if ever, material net cash inflows may commence from any of our other drug candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- § the number of clinical sites included in the trials;
- § the length of time required to enroll suitable patients;
- § the number of patients that ultimately participate in the trials;
- § the number of doses patients receive;
- § the duration of patient follow-up; and
- § the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the terms and timing of regulatory approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving regulatory approval for any of our drug candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some drug candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or other regulatory authorities were to require us to conduct clinical trials beyond those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development. Drug commercialization will take several years and millions of dollars in development costs.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance and legal functions, including stock-based compensation, travel expenses and recruiting expenses. Other general and administrative expenses include facility related costs, patent filing and prosecution costs and professional fees for marketing, legal, auditing and tax services, insurance costs, as well as payments made under our related-party services agreement and milestone payments under our finder's services agreement.

We anticipate that our general and administrative expenses will increase as a result of increased payroll, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company. We anticipate the additional costs for these services will increase our general and administrative expenses by approximately \$1.0 million to \$2.0 million on an annual basis. Additionally, if and when we believe a regulatory approval of a drug candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our drug candidates.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities.

Income Taxes

Since our inception in 2012, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2014, we had federal and state net operating loss carryforwards of \$13.8 million and \$13.8 million, respectively, both of which begin to expire

in 2032. As of December 31, 2014, we also had federal research and development tax credit carryforwards of \$0.2 million, which begin to expire in 2032, and we had no state research and development tax credit carryforwards.

Critical Accounting Policies and Significant Judgments and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reported period. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions and conditions.

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

Accrued Research and Development Expenses

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

- § vendors in connection with the preclinical development activities;
- § contract manufacturers in connection with commercial scale-up activities and the production of preclinical and clinical trial materials;
- § CROs in connection with clinical trials; and
- § investigative sites in connection with clinical trials.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or prepaid accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, we have not made any material adjustments to our prior estimates of accrued research and development expenses.

Stock-Based Compensation

We measure stock options and other stock-based awards granted to employees and directors based on the fair value on the date of grant and recognize the corresponding compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, we issue stock options and restricted stock awards with only service-based vesting conditions and record the expense for these awards using the straight-line method.

We measure stock-based awards granted to consultants and non-employees based on the fair value of the award on the date at which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model, which uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected terms of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield.

As there has been no public market for our common stock to date, the estimated fair value of our common stock has been determined by our board of directors, with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. We have periodically determined the estimated fair value of our common stock at various dates using contemporaneous valuations performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*.

Our common stock valuations were performed using a hybrid method, which used market approaches to estimate our enterprise value. We selected the hybrid method based on the availability and the quality of information to develop the assumptions for the methodology. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more of the scenarios is calculated using an option-pricing method, or OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. Under this method, the common stock value is based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available, as well as the rights of each class of stock. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceed the value of the preferred stock liquidation preference at the time of a liquidity event, such as a strategic sale or merger.

In the hybrid method used in each of our third-party valuations, six types of future-event scenarios were considered: two different OPM scenarios, a strategic sale scenario, a low-value and a high-value IPO scenario, and a liquidation scenario. The relative probability of each type of future-event scenario was based on our analysis of market conditions at the time, including then-current IPO valuations of similarly situated companies and expectations as to the timing and likely prospects of the future-event scenarios. To determine our enterprise values under the two OPM scenarios, we used the OPM backsolve approach. To determine our enterprise values under the two IPO scenarios, we used the guideline public company method under the market approach, which analyzed enterprise values at the IPO date of publicly traded dermatology-focused biopharmaceutical companies. To determine our enterprise value under the strategic sale scenario, we considered sale transactions of comparable companies. Finally, to determine our

enterprise value for the liquidation scenario, we assumed a sale at the net book value of our assets and liabilities. To derive the fair value of the common stock for each future-event scenario under the hybrid method, the proceeds to the common stockholders were calculated based on the conversion rights and preferences of the preferred stock. We then applied a discount for lack of marketability to the common stock to account for the lack of access to an active public market.

We performed these contemporaneous valuations, with the assistance of a third-party valuation specialist, as of December 1, 2013, June 30, 2014 and December 8, 2014. In addition to these valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, including:

- § the prices at which we sold shares of preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- § the progress of our research and development programs, including the status of preclinical studies and clinical trials for our drug candidates;
- § our stage of development and commercialization and our business strategy;
- § external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- § our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- § the lack of an active public market for our common stock and our preferred stock;
- § the likelihood of achieving a liquidity event, such as an initial public offering, or IPO, or sale of our company in light of prevailing market conditions; and
- § the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

Following the closing of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

The following table summarizes by grant date the number of shares subject to options granted since January 1, 2014, the per share exercise price of the options, the fair value of common stock underlying the options on date of grant and the per share estimated fair value of the options:

Grant Date	Number of Shares Subject To Options Granted	Per Share Exercise Price of Options	Fair Value of Common Stock per Share on Option Grant Date	Per Share Estimated Fair Value of Options
January 29, 2014	180,000	\$ 0.12	\$ 0.12	\$ 0.10
August 13, 2014	400,000	\$ 0.21	\$ 0.41 ⁽¹⁾	\$ 0.37
December 8, 2014	1,145,961	\$ 0.44	\$ 0.53 ⁽²⁾	\$ 0.46

⁽¹⁾ At the time of the option grants on August 13, 2014, our board of directors determined that the fair value of our common stock of \$0.21 per share calculated in the contemporaneous valuation as of June 30, 2014 reasonably reflected the per share fair value of common stock as of the grant date. However, as described below, the fair value of common stock at the date of these grants was adjusted to \$0.41 per share in connection with a retrospective fair value assessment for accounting purposes.

- (2) At the time of the option grants on December 8, 2014, our board of directors determined that the fair value of our common stock of \$0.44 per share calculated in the contemporaneous valuation as of December 8, 2014 reasonably reflected the per share fair value of common stock as of the grant date. However, as described below, the fair value of common stock at the date of these grants was adjusted to \$0.53 per share in connection with a retrospective fair value assessment for accounting purposes.

In the course of preparing for this offering, in March 2015, we performed a retrospective fair value assessment and concluded that the fair value of our common stock underlying stock options we granted in August 2014 was \$0.41 per share for accounting purposes and that the fair value of our common stock underlying stock options we granted in December 2014 was \$0.53 per share for accounting purposes. These reassessed values, which we applied to determine the fair values of the August 2014 and December 2014 option grants to determine stock-based compensation expense for accounting purposes, were based in part upon revised valuations of our common stock as of June 30, 2014 and December 8, 2014, performed on a retrospective basis with the assistance of a third-party specialist, taking into account an increased probability of executing a successful initial public offering in 2015 and an increased probability of a successful result in our Phase 2 clinical trial of A-101 in patients with SK on the trunk and extremities. These revised common stock valuations were performed using the hybrid method.

Results of Operations

Comparison of Years Ended December 31, 2013 and 2014

The following table summarizes our results of operations for the years ended December 31, 2013 and 2014:

	Year Ended December 31,		Change
	2013	2014	
Revenue	\$ —	\$ —	\$ —
Operating expenses:		(in thousands)	
Research and development	3,488	6,507	3,019
General and administrative	1,769	2,026	257
Total operating expenses	5,257	8,533	3,276
Loss from operations	(5,257)	(8,533)	(3,276)
Interest income	21	16	(5)
Net loss	\$ (5,236)	\$ (8,517)	\$ (3,281)

Research and Development Expenses

Research and development expenses were \$3.5 million for the year ended December 31, 2013, compared to \$6.5 million for the year ended December 31, 2014. The increase of \$3.0 million was primarily attributable to an increase of \$3.1 million in direct costs associated with the three Phase 2 clinical trials of our lead drug candidate, A-101 for the treatment of SK, being conducted during the year, comprised of increases of \$1.9 million in clinical expenses, \$1.1 million in manufacturing scale-up expenses and \$0.1 million in development-related expenses. We also had an increase of \$0.1 million in personnel-related expenses. These increases were partially offset by a decrease of \$0.2 million in expenses due to a \$0.2 million milestone payment made in 2013 under our assignment agreement, compared to no milestone payments made in 2014.

General and Administrative Expenses

General and administrative expenses were \$1.8 million for the year ended December 31, 2013, compared to \$2.0 million for the year ended December 31, 2014. The increase of \$0.2 million was primarily attributable to increases of \$0.1 million in market research expenses and \$0.1 million in related-party management services.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred net losses and negative cash flows from our operations. We have financed our operations since inception through sales of our redeemable convertible preferred stock, receiving aggregate gross proceeds of \$31.5 million.

As of December 31, 2014, we had cash, cash equivalents and marketable securities of \$16.6 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our lease obligations.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2013 and 2014:

	Year Ended December 31,	
	2013	2014
	(in thousands)	
Cash used in operating activities	\$ (4,920)	\$ (7,636)
Cash used in investing activities	(4,535)	(1,779)
Cash provided by financing activities	—	10,584
Net increase (decrease) in cash and cash equivalents	\$ (9,455)	\$ 1,169

Operating Activities. During the year ended December 31, 2014, operating activities used \$7.6 million of cash, primarily resulting from our net loss of \$8.5 million and non-cash charges of \$0.1 million, partially offset by cash provided by changes in our operating assets and liabilities of \$0.8 million. Net cash provided by changes in our operating assets and liabilities during the year ended December 31, 2014 consisted primarily of a \$0.8 million increase in accounts payable and a \$0.2 increase in accrued expenses, partially offset by a \$0.2 million increase in prepaid expenses and other current assets. The increases in accounts payable and accrued expenses were primarily due to higher clinical trial costs incurred in 2014 than in 2013 related to A-101. The increase in prepaid expenses and other current assets was primarily due to a prepayment for manufacturing scale-up expenses.

During the year ended December 31, 2013, our operating activities used \$4.9 million of cash, primarily resulting from our net loss of \$5.2 million, partially offset by cash provided by net changes in our operating assets and liabilities of \$0.3 million, which primarily consisted of an increase in accounts payable. The increase in accounts payable was primarily due to costs incurred in connection with the commencement of preclinical studies and a clinical trial of A-101 in 2013.

Investing Activities. During the year ended December 31, 2014, we used cash of \$1.8 million in investing activities, consisting of purchases of marketable securities of \$5.0 million and purchases of equipment of \$0.4 million, partially offset by proceeds from sales and maturities of marketable securities of \$3.7 million.

During the year ended December 31, 2013, we used cash of \$4.5 million in investing activities, consisting of purchases of marketable securities.

Financing activities. During the year ended December 31, 2014, net cash provided by financing activities was \$10.6 million as a result of net proceeds received from our issuance of Series B redeemable convertible preferred stock in September 2014. We had no cash flows from financing activities during the year ended December 31, 2013.

Funding Requirements

We plan to focus in the near term on the development, regulatory approval and potential commercialization of A-101 for the treatment of SK. We anticipate we will incur net losses for the next several years as we complete clinical development of A-101 for the treatment of SK and continue research and development of A-101 for the treatment of common warts and A-102 for the treatment of SK and common warts. In addition, we plan to continue to invest in discovery efforts to explore additional drug candidates, potentially build commercial capabilities and expand our corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our drug candidates arising out of our current clinical trials when we expect, or at all.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support development of our drug candidates.

Following this offering, we will be a publicly traded company and will incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and The NASDAQ Stock Market, requires public companies to implement specified corporate governance practices that are currently inapplicable to us as a private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe that the anticipated net proceeds from this offering, together with our existing cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next _____ months, including the completion of our three planned Phase 3 clinical trials for A-101 for the treatment of SK, the submission of our NDA with the FDA for the approval of A-101 for the treatment of SK in the United States and the completion of our planned Phase 2 clinical trials for A-101 for the treatment of common warts. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect that we will require additional capital to commercialize A-101 for the treatment of SK, if we receive regulatory approval, and to pursue in-licenses or acquisitions of other drug candidates. If we receive regulatory approval for A-101 for the treatment of SK, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are unable to raise sufficient additional capital, we may need to substantially curtail our planned operations and the pursuit of our growth strategy.

We may raise additional capital through the sale of equity or convertible debt securities. In such an event, your ownership will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- § the number and characteristics of the drug candidates we pursue;
- § the scope, progress, results and costs of researching and developing our drug candidates, and conducting preclinical studies and clinical trials;
- § the timing of, and the costs involved in, obtaining regulatory approvals for our drug candidates;
- § the cost of manufacturing our drug candidates and any drugs we successfully commercialize;
- § our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- § the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- § the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future drug candidates, if any.

See "Risk Factors" for additional risks associated with our substantial capital requirements.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2014 and the effect such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1 - 3 Years	4 - 5 Years	More than 5 Years
	(in thousands)				
Operating lease commitments ⁽¹⁾	\$ 201	\$ 104	\$ 97	\$ —	\$ —
Total	<u>\$ 201</u>	<u>\$ 104</u>	<u>\$ 97</u>	<u>\$ —</u>	<u>\$ —</u>

⁽¹⁾ We lease office space in Malvern, Pennsylvania under an operating lease agreement that, as amended, expires in November 2016.

Under various agreements, we will be required to make milestone payments and pay royalties and other amounts to third parties. We have not included any contingent payment obligations, such as milestones or royalties, in the table above as the amount, timing and likelihood of such payments are not known.

Under the assignment agreement pursuant to which we acquired intellectual property, we have agreed to pay royalties on sales of A-101 or related products at rates ranging in low single-digit percentages of net sales, as defined in the agreement. Under the related finder's services agreement, we have agreed to make aggregate payments of up to \$1.3 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals, as described in the agreement. We have also agreed to make aggregate payments of up to \$4.5 million upon the achievement of specified commercial milestones. In addition, we have agreed to pay royalties on sales of A-101 or related products at a low single-digit percentage of net sales, as defined in the agreement.

Under a commercial supply agreement with a third party, we have agreed to pay a termination fee of up to \$0.4 million in the event we terminate the agreement without cause or the third party terminates the agreement for cause.

We enter into contracts in the normal course of business with CROs for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Off-Balance Sheet Arrangements

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

Recently Issued and Adopted Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU 2014-10, *Development Stage Entities*. The amendments in this update removed all incremental financial reporting requirements, including inception-to-date information and certain other disclosures currently required under GAAP, in the financial statements of development stage companies. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim reporting periods beginning after December 15, 2015. Early adoption is permitted. We elected to early adopt this guidance and, therefore, have not presented inception-to-date information and other related disclosures in our financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted. We are currently evaluating the potential impact of the adoption of this standard, but we believe its adoption will have no impact on our financial position, results of operations or cash flows.

Quantitative and Qualitative Disclosures about Market Risks

We are exposed to market risk related to changes in interest rates. Our cash, cash equivalents and marketable securities consist of money market funds, corporate debt securities and government agency debt. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. However, due to the short-term nature and low-risk profile of our investment portfolio, we do not expect that an immediate 10% change in market interest rates would have a material effect on the fair market value of our investment portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have irrevocably elected to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards when they are required to be adopted by public companies that are not emerging growth companies.

BUSINESS

Overview

We are a clinical-stage specialty pharmaceutical company focused on identifying, developing and commercializing innovative and differentiated topical drugs to address significant unmet needs in dermatology. Our lead drug candidate, A-101, is a proprietary high-concentration hydrogen peroxide topical solution that we are developing as a prescription treatment for seborrheic keratosis, or SK, a common non-malignant skin tumor. We have completed three Phase 2 clinical trials of A-101 in over 300 patients with SK. In these trials, following one or two applications of A-101, we observed clinically relevant and statistically significant improvements in clearing SK lesions on the face, trunk and extremities of the body. Clinically relevant means that the observed results suggest a potential meaningful medical benefit, and statistically significant means that there is a low statistical probability, typically less than 5%, that the observed results occurred by chance alone. We plan to commence three Phase 3 clinical trials of A-101 in patients with SK in the second half of 2015 and, if the results of these trials are favorable, to submit a New Drug Application, or NDA, for A-101 for the treatment of SK to the U.S. Food and Drug Administration, or FDA, in the first half of 2016. We also intend to develop A-101 as a prescription treatment for common warts and A-102, a proprietary gel dosage form of hydrogen peroxide, as a prescription treatment for SK and common warts. In addition, we intend to in-license or acquire additional drug candidates for other dermatological conditions to build a fully integrated dermatology company.

SK lesions are among the most common non-malignant skin tumors and one of the most frequent diagnoses made by dermatologists. SK lesions typically have a waxy, scaly, slightly elevated appearance, and multiple lesions are often present. Though the lesions are non-malignant, patients often elect to have their condition treated by a dermatologist, either because the lesions have become inflamed or because the patient feels they are cosmetically unattractive. SK lesions are usually treated by cryosurgery, electrodesiccation, curettage or excision. Each of these methods may be painful or can result in pigmentary changes or scarring at the treatment site. No drugs have been approved by the FDA for the treatment of SK.

A study published in the Journal of The American Academy of Dermatology in 2006, which we refer to as the AAD study, estimated that SK affects over 83 million people in the United States. Based on a market survey we commissioned in 2014, we estimate that there are 18.5 million patient visits to dermatologists for SK and dermatologists perform approximately 8.3 million procedures to remove SK lesions annually in the United States. We estimate that the cost of these procedures to third-party payors and patients is more than \$1.2 billion annually.

In June 2014, we completed our Phase 2 clinical trial of A-101 in 35 patients with four SK lesions on the trunk; in December 2014, we completed our Phase 2 clinical trial of A-101 in 172 patients with four SK lesions on the trunk or extremities; and in March 2015, we completed our Phase 2 clinical trial of A-101 in 119 patients with a single SK lesion on the face. In each of these trials, following one or two applications of the two highest concentrations of A-101, we observed clinically relevant and statistically significant improvements in clearing SK lesions.

We held an end-of-Phase 2 meeting with the FDA in May 2015. Based on the FDA's feedback regarding our proposed design of the three planned Phase 3 clinical trials of A-101 in patients with SK lesions on the face, trunk and extremities, we plan to commence these trials in the second half of 2015. If the results of the Phase 3 clinical trials are favorable, we intend to submit our NDA for A-101 for the treatment of SK to the FDA in the first half of 2016 and build a specialty sales force to market the product to dermatologists in the United States. We have also requested scientific advice from the European Medicines Agency, or EMA, for A-101 for the treatment of SK. We plan to seek a collaborator to commercialize A-101, if approved, in the European Union. We have the exclusive right to commercialize A-101, if approved, throughout the world.

We also plan to develop A-101 for the treatment of common warts. Although common warts are generally not harmful and in most cases eventually clear without any medical treatment, they may be painful and aesthetically unattractive and are contagious. On an annual basis, 1.9 million people are diagnosed with common warts. The AAD study estimated that annual direct expenditures for patients seeking treatment for warts of all types in a medical office were \$939 million, including the cost of the office visit as well as the

treatments. We estimate that approximately one-half of those expenditures were for the treatment of common warts. Common warts can be removed with slow-acting, over-the-counter products containing salicylic acid. As with SK, cryosurgery is the most frequently used in-office treatment for common warts. No prescription drugs have been approved by the FDA for the treatment of common warts. We are conducting toxicology studies and plan to commence Phase 2 clinical trials of A-101 for the treatment of common warts in the second half of 2015. In addition to A-101, we are also developing A-102, a proprietary topical gel dosage form of hydrogen peroxide, for the treatment of both SK and common warts.

Our intellectual property portfolio contains issued patents directed to methods of use for A-101. Our issued patents begin to expire in 2022, subject to any applicable patent term adjustment or extension. Our intellectual property portfolio also contains provisional patent applications directed to, among other things, formulations and methods of use for A-101 and a single-use, self-contained, pre-filled, disposable pen-type applicator. Our pending U.S. provisional patent applications, if they issue as patents, would be expected to expire beginning in 2035. We intend to file two non-provisional patent applications in the second quarter of 2015 for our formulations and methods of use for A-101 and our pen-type applicator.

Corporate History and Management Experience

We were founded in 2012 and are headquartered in Malvern, Pennsylvania. Our management team has extensive experience in dermatological product development from drug discovery through commercialization, with experience as practicing dermatologists and in leadership roles at a number of dermatology companies. Members of our management team founded and led Vicept Therapeutics, Inc., a dermatology company that was acquired by Allergan, Inc. in 2011. In addition, several of our management team members worked together at CollaGenex Pharmaceuticals, Inc., a dermatology-focused specialty pharmaceutical company that was acquired by Galderma Laboratories, LP in 2008, and Trigenesis Therapeutics, Inc., a dermatology company that was acquired by Dr. Reddy's Laboratories Inc. in 2004. We believe that the experience of our management team and our broad network of relationships with leaders within the industry and medical community provides us with insight into product development and identification of other commercial opportunities in dermatology.

Our Drug Candidates

We have utilized our experience to establish a pipeline of drug candidates that we believe will address significant unmet needs in dermatology. Our pipeline of drug candidates is summarized in the table below:

Drug Candidate	Preclinical	Phase 1	Phase 2	Phase 3
A-101 (Topical solution for treatment of SK)				★
A-101 (Topical solution for treatment of common warts)			◆	
A-102 (Gel dosage form for treatment of SK)				
A-102 (Gel dosage form for treatment of common warts)				

★ Plan to commence Phase 3 clinical trials in second half of 2015

◆ Toxicology studies ongoing; plan to commence Phase 2 clinical trials in second half of 2015

Our Strategy

Our goal is to develop and commercialize innovative and differentiated dermatology products that address significant unmet medical needs. The key components of our strategy to achieve this goal are to:

- § **Complete Clinical Development and Obtain Regulatory Approval for A-101 for the Treatment of SK.** We plan to focus in the near term on the development, regulatory approval and potential commercialization of A-101 for the treatment of SK. We recently held an end-of-Phase 2 meeting for A-101 with the FDA in May 2015. Based on the FDA's feedback at that meeting, we plan to commence three Phase 3 clinical trials in the second half of 2015 for the treatment of SK on the face, trunk and extremities. If the results of these clinical trials are favorable, we intend to submit our NDA for A-101 for the treatment of SK to the FDA in the first half of 2016. We have also requested scientific advice from the EMA for A-101 for the treatment of SK.
- § **Develop A-101 for the Treatment of Common Warts and Develop Our Other Drug Candidates.** We are conducting toxicology studies and plan to commence Phase 2 clinical trials of A-101 for the treatment of common warts in the second half of 2015. In addition to A-101, we are also developing A-102 for the treatment of SK and common warts.
- § **Build a Specialized Sales and Marketing Organization.** We intend to commercialize our dermatology products, if approved, by building a specialized sales and marketing organization focused solely on dermatologists and their patients in the United States. We believe a scientifically oriented, customer-focused team of approximately 45 sales representatives would allow us to reach the approximately 5,000 dermatologists in the United States with the highest potential for using A-101.
- § **In-license or Acquire Additional Drug Candidates to Build a Fully Integrated Dermatology Company.** We intend to in-license or acquire drug candidates for other dermatological conditions from a number of sources by leveraging the insights, network and experience of our management team. We will seek to maintain a well-balanced portfolio by in-licensing or acquiring additional drug candidates across various stages of development. We intend to focus on drug candidates that we believe have streamlined clinical development and regulatory pathways, including drug candidates that we believe have attractive profiles in early clinical testing and that we can advance into late-stage development. We may also seek to in-license or acquire dermatology products that have received regulatory approval in order to accelerate our commercial entry into the market or to expand the portfolio of products we can market to dermatologists. We have not entered into any collaboration or licensing agreements or acquired any additional drug candidates to date.

Our Lead Drug Candidate: A-101 for the Treatment of Seborrheic Keratosis

Overview

We are developing A-101 for the treatment of SK. SK lesions typically have a waxy, scaly, slightly elevated appearance, and multiple lesions are often present. The lesions can vary in color from light tan to dark brown or black and typically appear on the face, trunk and extremities. Though the lesions are non-malignant, patients often elect to have their condition treated by a dermatologist, either because the lesions have become inflamed or because the patient feels they are cosmetically unattractive.

We have completed three Phase 2 clinical trials in over 300 patients with SK and observed clinically relevant and statistically significant improvements in clearing SK lesions on the face, trunk and extremities

of the body following one or two applications of A-101. The following table summarizes the design of these clinical trials:

Name of Clinical Trial and Number of Subjects Enrolled	SK Lesion Area	Date Completed	Trial Design	Trial Objective
SEBK-203 (n=119)	Face	March 2015	§ Multicenter, randomized, double-blinded, vehicle-controlled, parallel group § One lesion treated § A-101 concentrations: 32.5%, 40.0% § Duration: 106 days	§ Evaluate safety, efficacy, tolerability and dose-response profile of two concentrations of A-101 vs. vehicle control
SEBK-202 (n=172)	Trunk and Extremities	December 2014	§ Multicenter, randomized, double-blinded, vehicle-controlled, parallel group § Four lesions treated § A-101 concentrations: 32.5%, 40.0% § Duration: 106 days	§ Evaluate safety, efficacy, tolerability and dose-response profile of two concentrations of A-101 vs. vehicle control
SEBK-201 (n=35)	Trunk (Back)	June 2014	§ Double-blind, vehicle-controlled intra-subject § Four lesions treated § A-101 concentrations: 25.0%, 32.5%, 40.0% § Duration: 78 days	§ Evaluate safety, efficacy and tolerability of three concentrations of A-101 vs. vehicle control

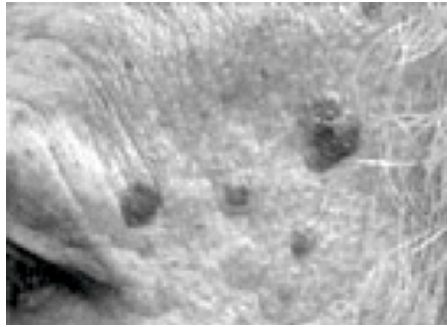
Market Overview

SK lesions are among the most common non-malignant skin tumors. Patients may be affected with just one SK lesion or dozens of SK lesions. SK lesions do not pose a health risk, although the lesions can become inflamed, which may lead to itching and bleeding from scratching or friction from clothing or shaving. SK lesions may appear to be skin cancer lesions and the presence of the lesions often motivates patients to seek a diagnosis, usually from a dermatologist. SK generally appears in middle-aged persons and the incidence of SK increases with age.

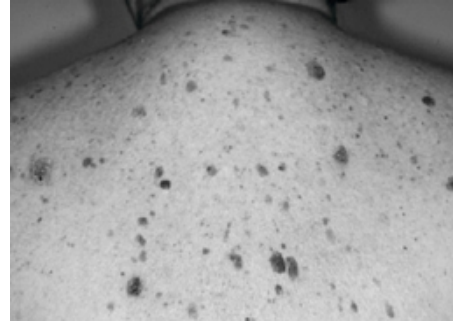
A study published in the Journal of The American Academy of Dermatology in 2006 estimated that SK affects over 83 million people in the United States. Based on a market survey we commissioned in 2014, we estimate that there are 18.5 million patient visits to dermatologists for SK and dermatologists perform approximately 8.3 million procedures to remove SK lesions annually in the United States. We estimate that the cost of these procedures to third-party payors and patients is more than \$1.2 billion annually. We believe this market will grow if dermatologists have access to treatments that have better aesthetic outcomes, are less-invasive, cause minimal discomfort and can be administered by non-physician staff to treat multiple lesions.

The following pictures illustrate patients with SK lesions on the face and the back:

Face



Back



Limitations of Current Treatment Options for Seborrheic Keratosis

There are currently no FDA-approved drugs for the treatment of SK. However, dermatologists typically choose SK treatment based on a number of factors, including disease severity, patient characteristics and patient preference. The following table sets forth the most commonly used treatment options, the circumstances under which each procedure is typically used, and the key advantages, key drawbacks and frequency of use of each procedure:

Current Treatment Options for Seborrheic Keratosis

Procedure	Description	When Used	Key Advantages	Key Drawbacks	Frequency of Use
Cryosurgery	<ul style="list-style-type: none"> § Spraying liquid nitrogen at a temperature of approximately negative 320 degrees Fahrenheit directly onto the SK lesions § Lesion falls off once frozen 	<ul style="list-style-type: none"> § Lighter-skinned patients § Multiple lesions 	<ul style="list-style-type: none"> § Easy, quick and inexpensive § Rarely causes bleeding and requires minimal wound care 	<ul style="list-style-type: none"> § Frequently painful § Multiple treatments may be required § Potential hypopigmentation § Potential scarring, pain and swelling § Requires physician to perform procedure 	<ul style="list-style-type: none"> § Approximately two-thirds of treated SK patients
Curettage	<ul style="list-style-type: none"> § Scraping SK lesions off with the use of a tool known as a curette 	<ul style="list-style-type: none"> § Single or multiple thin lesions § In combination with electrodesiccation for thick lesions § In combination with cryosurgery 	<ul style="list-style-type: none"> § May quickly remove single or multiple growths 	<ul style="list-style-type: none"> § Requires local anesthesia § Potential bleeding and minor infection § Requires physician to perform procedure 	<ul style="list-style-type: none"> § 5% to 10% of treated SK patients
Electrodesiccation	<ul style="list-style-type: none"> § Using an electric needle to burn off the SK lesion 	<ul style="list-style-type: none"> § Small and facial lesions § Darker skinned patients § In combination with curettage for thick lesions 	<ul style="list-style-type: none"> § Fast healing § Minimal scarring § Less risk of hypopigmentation than cryosurgery 	<ul style="list-style-type: none"> § More time-intensive than alternatives § May require local anesthesia § Requires electrosurgical equipment § Potential bleeding, infection and darkening of skin in treatment area § Requires physician to perform procedure 	<ul style="list-style-type: none"> § 5% to 10% of treated SK patients
Excision	<ul style="list-style-type: none"> § Removing entire lesion with a scalpel 	<ul style="list-style-type: none"> § Raised or thick lesions § In cases of clinical uncertainty where a biopsy is needed to confirm diagnosis 	<ul style="list-style-type: none"> § Covered by insurance when a biopsy is needed 	<ul style="list-style-type: none"> § Requires local anesthesia § Requires wound management § Potential infection § More expensive than other alternatives § Requires physician to perform procedure 	<ul style="list-style-type: none"> § 5% to 10% of treated SK patients

Cryosurgery, which involves spraying liquid nitrogen at a temperature of negative 320 degrees Fahrenheit directly onto the SK lesions, is used in approximately two-thirds of treated SK patients. In this procedure, the lesion is frozen and subsequently falls off. Dermatologists use cryosurgery because it is easy, quick and inexpensive. However, depending on the severity of the patient's condition, more than one cryosurgery treatment is typically required to remove all of the targeted lesions. Adverse effects experienced by patients using cryosurgery include permanent hypopigmentation, or loss of skin color, hyperpigmentation, or darkening of the skin, scarring, pain and edema, or swelling.

Other treatments include curettage, or scraping, as well as electrodesiccation and excision. We estimate that each of these treatments is used for 5% to 10% of treated SK patients. Curettage involves scraping SK lesions off with the use of a tool known as a curette. As a result, this procedure typically leads to bleeding, may result in infection and requires a longer time for the skin to heal. Electrodesiccation is a form of electrosurgery that involves the use of an electric needle to burn off the SK lesion. Although labor- and time-intensive, this procedure is sometimes used for darker-skinned patients in order to avoid the permanent hypopigmentation or scarring that can occur with other procedures. With an excision procedure, the lesion is removed with a scalpel but remains intact for biopsy in cases where a definitive diagnosis has not been made. These procedures are sometimes used in combination to remove SK lesions. In addition, there are other dermatological treatments that are used less frequently.

A-101 Mechanism of Action

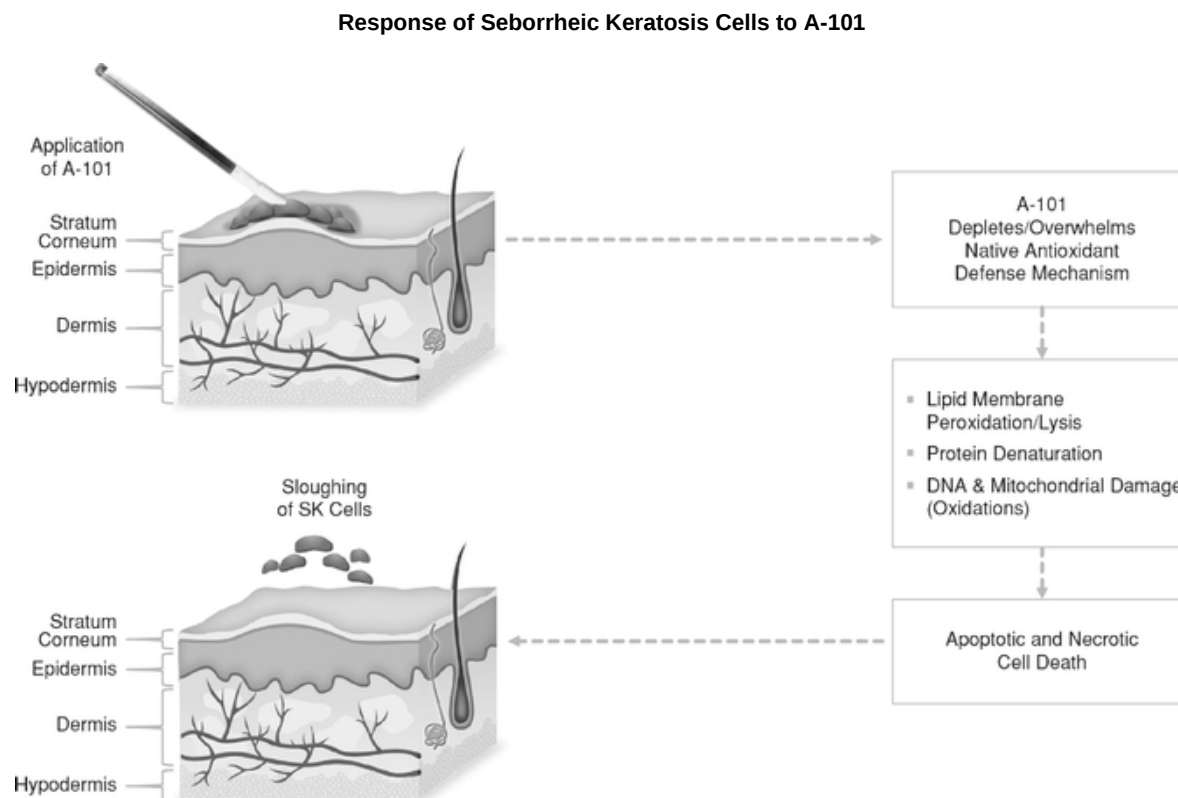
SK is a slowly growing epidermal tumor consisting of an abnormal accumulation of hyper-adherent senescent cells exhibiting decreased cell death. Senescent cells are no longer capable of dividing but are still alive and metabolically active. SK lesions may be amenable to a topically delivered agent that could both break down the abnormal intercellular connections between the cells and promote death of the abnormal SK cells.

Hydrogen peroxide is a potent and important oxidizing agent in the human body. Local concentrations of hydrogen peroxide are carefully controlled by a complex antioxidant defense system consisting of both enzymes and nonenzymatic components. The topical application of high concentrations of hydrogen peroxide to SK lesions can locally overwhelm this antioxidant defense system in the skin, allowing hydrogen peroxide to penetrate the surface of the lesion, react with the abnormal SK cells, and remove or dissolve the SK lesions.

Through a process known as lipid peroxidation, free radical molecules generated by hydrogen peroxide degrade the phospholipids of the cell membrane, leading to the breakdown, or lysis, of the lipid membrane of the cell. This chemical reaction is followed by the denaturation, or loss of structure, of proteins within the cell, as well as oxidative DNA and mitochondrial damage. This series of events induces cell death of

abnormal SK cells, either through the process of programmed cell death, known as apoptosis, or through cell injury, known as necrosis.

The following graphic illustrates this mechanism of action for A-101:



Benefits of A-101

While traditional procedures for the treatment of SK have become useful options for dermatologists and their patients, they suffer from a number of limitations, including their poor aesthetic outcomes and pain profile. In some cases, these procedures are invasive, with the associated need for wound management and risk of infection. Many patients with SK remain unsatisfied with their treatment options. If A-101 is approved, we believe that it will offer the following potential benefits to dermatologists and their patients:

- § **Potential to be the First FDA-Approved Drug Treatment for SK.** There are currently no FDA-approved drugs for the treatment of SK. If A-101 is approved by the FDA, it has the potential to be the first drug approved for the treatment of SK in the United States, thereby providing dermatologists confidence in A-101 as a treatment option.
- § **Attractive Efficacy Profile.** In three Phase 2 clinical trials conducted to date in over 300 patients with A-101, we have observed clinically relevant and statistically significant clearance of SK lesions on the face, trunk and extremities after one or two applications.
- § **Non-invasive Treatment with Favorable Safety Profile.** In each of our clinical trials, A-101 was well tolerated and caused minimal discomfort, with most patients experiencing only mild, transient tingling upon application. A-101 was observed to be appropriate for all skin types tested and for use on the face. The most commonly used treatment procedure, cryosurgery, is a painful process. A-101 is a topically applied medication and does not require the use of local anesthesia, with its well-known risks. We believe A-101, if approved, will be an attractive treatment option for SK patients seeking an alternative that is non-invasive and reduces the risk of pigmentary changes, scarring, bleeding and other adverse side effects associated with current treatment procedures.

- § **Ease of Administration.** If approved, we expect that A-101 will be administered using a single-use, self-contained, pre-filled, disposable pen-type applicator, as an in-office treatment, without the need for anesthesia. After the initial diagnosis by a dermatologist, we expect that A-101 will be appropriate for administration by non-physician staff, thereby freeing up physician time.

Clinical Development

We submitted an IND for A-101 for the treatment of SK to the FDA in September 2013 and have completed three Phase 2 clinical trials under this IND. In February 2015, we held a Type C meeting with the FDA at which we discussed clinical endpoints to support a claim of efficacy, as well as the statistical methodology we plan to use in our Phase 3 clinical trials. In May 2015, we held an end-of-Phase 2 meeting with the FDA to discuss our A-101 development program leading to a potential NDA submission.

Phase 2 Clinical Trial of A-101 in Subjects with Seborrheic Keratosis on the Face (SEBK-203)

Trial Design

We commenced a Phase 2 clinical trial in October 2014 that was a multicenter, randomized, double-blind, vehicle-controlled, parallel group trial designed to evaluate the safety, tolerability, initial efficacy and dose-response profile of A-101 topical solution at 32.5% and 40.0% concentrations and a topical solution vehicle control. We completed the trial in March 2015. We enrolled 119 subjects in the trial at four sites in the United States, and 116 subjects completed the trial. Three of the 119 subjects withdrew from the trial due to unrelated adverse events. Of the 116 subjects who completed the trial, 37 subjects received the 40.0% concentration, 39 subjects received the 32.5% concentration and 40 subjects received the vehicle control. The age of the subjects ranged from 33 to 93, with a mean age of 70. Of the 116 subjects who completed the trial, 53 were male, 63 were female and all were Caucasian. Inclusion criteria included a clinical diagnosis of stable, clinically typical SK and one appropriate SK target lesion on the subject's face of specified size and thickness. Exclusion criteria included clinically atypical or rapidly growing SK lesions and the use of specified topical or systemic therapies within defined time period prior to the first visit.

The evaluation period consisted of 15 weeks after initial treatment. At the first visit, the investigator identified a single target lesion on the face of each subject for treatment. During the second visit, or baseline, which occurred on Day 1 of the evaluation period, eligible subjects were randomized to receive the vehicle control or one of the two active concentrations of A-101 and the applications were performed by non-physician staff. No applications were made at a visit on Day 8. At Day 22, any target lesion that met the retreatment criteria received a second application of the assigned concentration of A-101 or vehicle control. The subjects were evaluated at multiple visits through Day 106, but no applications were made after Day 22.

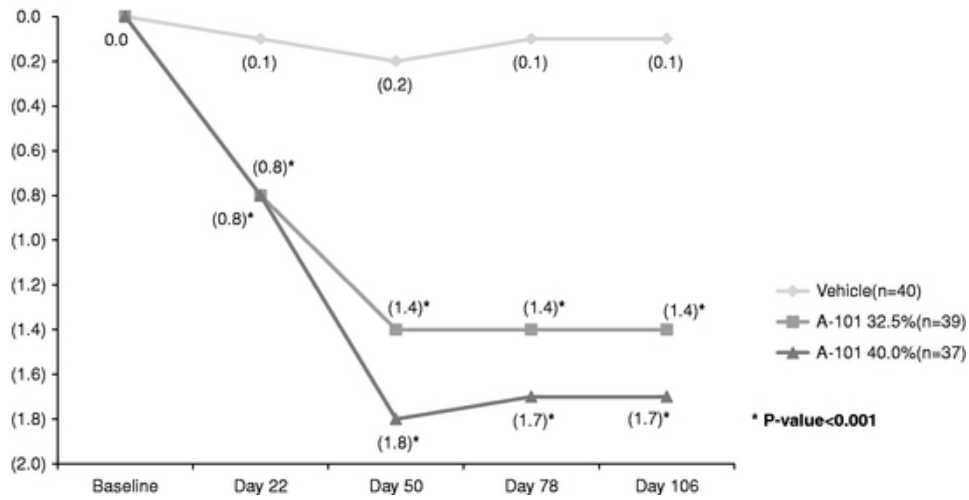
Endpoints

The primary endpoint of this clinical trial was the mean change from baseline in the Physician's Lesion Assessment, or PLA, score at the end of the trial. The PLA score is a method we developed to measure the severity of lesions and uses a scale ranging from zero to three. Secondary endpoints included responder analysis of PLA scores of zero or one. In this trial, a PLA score of zero represented no visible lesion, a PLA score of one represented a visible lesion that, while not elevated, has a surface appearance that is different from the surrounding skin, a PLA score of two represented a visible lesion that is elevated but with a thickness of less than or equal to one millimeter, and a PLA score of three represented a visible lesion with a thickness exceeding one millimeter.

Efficacy Results

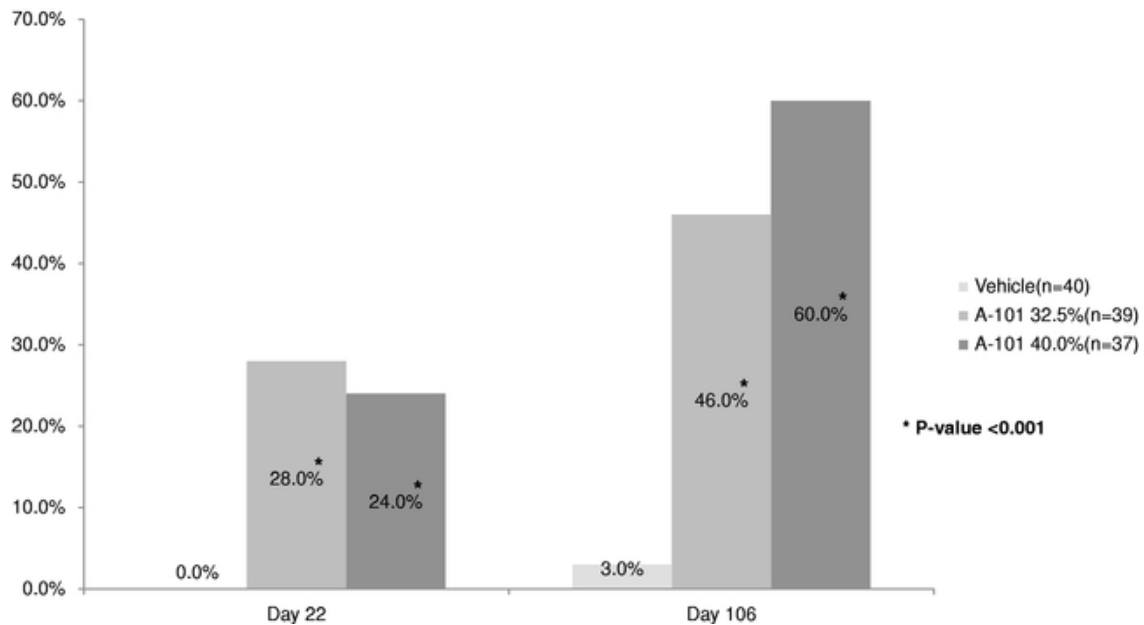
As shown in the table below, for the primary endpoint, mean change from baseline in PLA score, we observed statistically significant improvements as compared to the vehicle for both concentrations of A-101 evaluated, with the 40.0% concentration being the most effective. The results for the active treatment groups were statistically significant with a p-value of less than 0.001. P-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of 0.05 or less is generally considered to represent statistical significance, meaning that there is a less than 1-in-20 likelihood that the observed results occurred by chance.

Mean Change from Baseline in PLA Score — Face



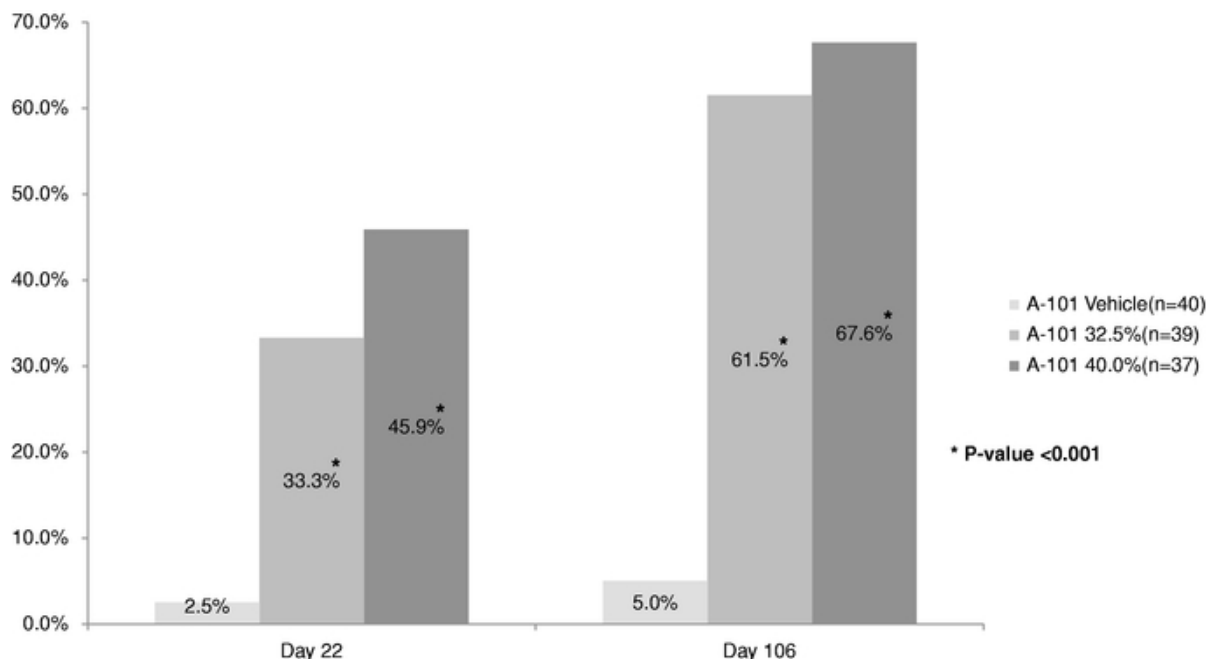
In addition, we measured the percentage of subjects who achieved total clearance, or a PLA of zero, at Day 22 and Day 106. These results are presented in the table below. At Day 22, 24.0% of the subjects receiving A-101 at the 40.0% concentration achieved total clearance and 28.0% of the subjects receiving A-101 at the 32.5% concentration achieved total clearance, compared to none in the vehicle control group. At Day 106, 60.0% of the subjects receiving A-101 at the 40.0% concentration achieved total clearance and 46.0% of subjects receiving A-101 at the 32.5% concentration achieved total clearance, compared to 3.0% in the vehicle control group. These results were statistically significant, with a p-value of less than 0.001.

Percentage of Subjects with Clear Lesions — Face



We also measured the percentage of subjects who achieved either total clearance or near clearance, or a PLA score of either zero or one, at Day 22 and Day 106. These results are presented in the table below. At Day 22, 45.9% of the subjects receiving A-101 at the 40.0% concentration achieved total clearance or near clearance and 33.3% of the subjects receiving A-101 at the 32.5% concentration achieved total clearance or near clearance, compared to 2.5% in the vehicle control group. At Day 106, 67.6% of the subjects receiving A-101 at the 40.0% concentration achieved total clearance or near clearance and 61.5% of subjects receiving A-101 at the 32.5% concentration achieved total clearance or near clearance, compared to 5.0% in the vehicle control group. These results were statistically significant, with a p-value of less than 0.001.

Percentage of Subjects with Clear or Near-Clear Target Lesions — Face



Safety Results

A-101 was generally well tolerated at both the 32.5% and 40.0% concentrations. While two subjects in each of the 32.5% and 40.0% concentration treatment groups reported severe stinging after administration, most local skin reactions were considered to be transient and mild or moderate. Treatment-emergent adverse events were reported by 29 subjects. However, only one of these adverse events, slight bleeding at the sight of administration, was determined by the investigator to be drug-related. Four subjects reported serious adverse events, but none were considered to be related to treatment by the investigator. Three subjects dropped out of the trial due to adverse events unrelated to treatment.

Phase 2 Clinical Trial of A-101 in Subjects with Seborrheic Keratosis on the Trunk and Extremities (SEBK-202)

Trial Design

In June 2014, we commenced a Phase 2 clinical trial that was a multicenter, randomized, double-blind, vehicle-controlled, parallel group trial designed to evaluate the safety, tolerability, initial efficacy and dose-response profile of A-101 topical solution with concentrations of 32.5% and 40.0% and a topical solution vehicle control. We completed the trial in December 2014. We enrolled 172 subjects in the trial at five sites in the United States, and 169 subjects completed the trial. Of the 172 subjects enrolled in the trial, 57 subjects received the 40.0% concentration, 57 subjects received the 32.5% concentration and 58

subjects received the vehicle control. Of the three subjects who withdrew from the trial, one subject withdrew due to inconvenience, one subject moved and one subject withdrew due to lack of follow-up by the investigator. The age of the subjects ranged from 48 to 97, with a mean age of 69. Of the 172 subjects enrolled in the trial, 91 were male, 81 were female and all but two were Caucasian. There were a variety of skin types within the trial population. Inclusion criteria included a clinical diagnosis of stable, clinically typical SK and at least four SK target lesions on the subject's trunk, defined as the upper body excluding the head and limbs, or extremities with a PLA of at least 2.0 and of specified size and thickness. Exclusion criteria included clinically atypical or rapidly growing SK lesions and the use of specified topical or systemic therapies within a defined time period prior to the first visit.

The evaluation period consisted of 15 weeks after initial treatment. At the first visit, the investigator identified four target lesions on the trunk or extremities of each subject for treatment. During the second visit, or baseline, which occurred on Day 1 of the evaluation period, eligible subjects were randomized to receive the vehicle control or one of the two active concentrations of A-101 and the applications were performed by non-physician staff. No applications were made at a visit on Day 8. At Day 22, any target lesion that met the retreatment criteria received a second application of the assigned concentration of A-101 or vehicle control. The subjects were then evaluated at multiple visits through Day 106, but no applications were made after Day 22.

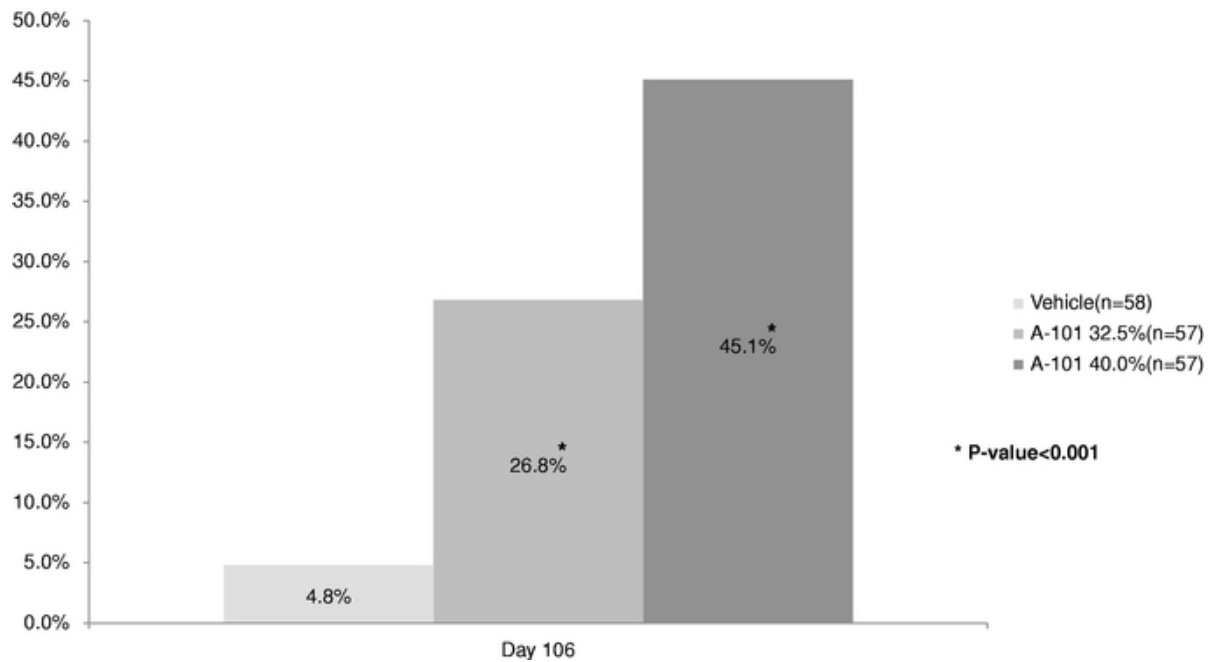
Endpoints

The primary endpoint of this clinical trial was the percentage of the four target SK lesions judged to be clear, meaning a PLA of zero, for each patient at the end of the trial. Secondary endpoints included the change from baseline PLA. In this trial, we used the same PLA score we used in our trial in subjects with SK lesions on the face (SEBK-203).

Efficacy Results

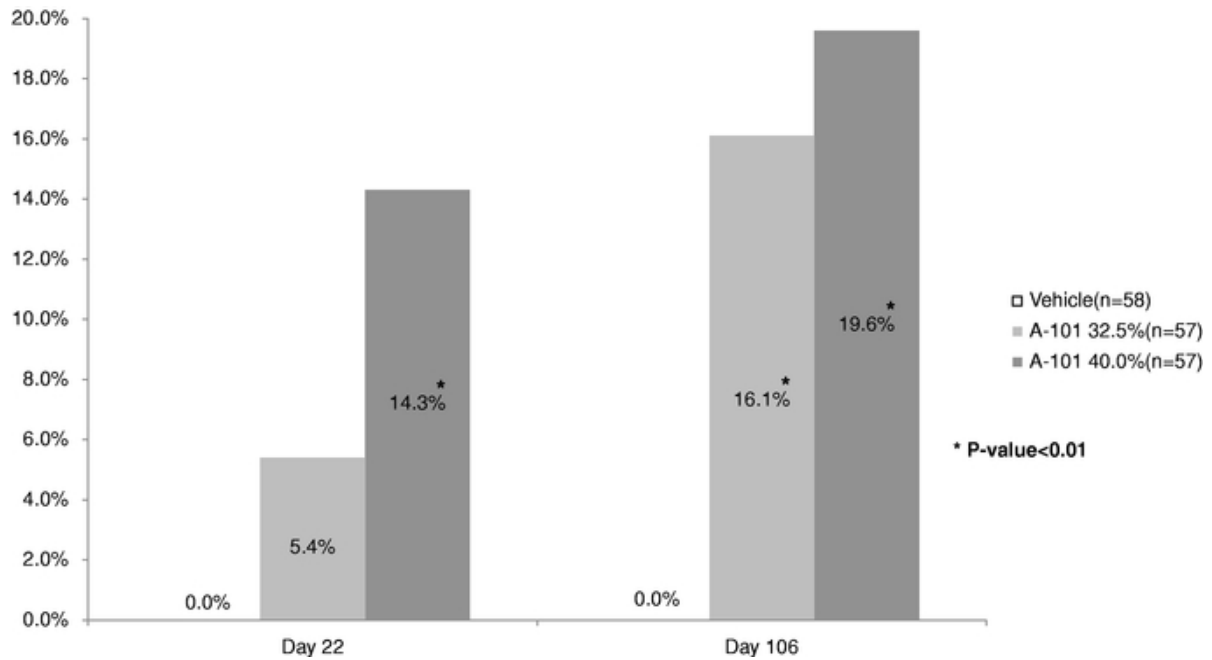
As shown in the table below, for the primary endpoint, the mean percentage of the four target SK lesions that were judged to be cleared for each patient at Day 106, we observed clinically relevant and statistically significant improvement for both concentrations of A-101 evaluated, with mean per-subject clearance of 26.8% and 45.1% at the 32.5% and 40.0% concentrations, respectively, compared to only 4.8% mean per-subject clearance in the vehicle control group. The results for the active treatment groups were statistically significant with a p-value of less than 0.001.

Mean Per-Subject Percentage Clearance — Trunk and Extremities



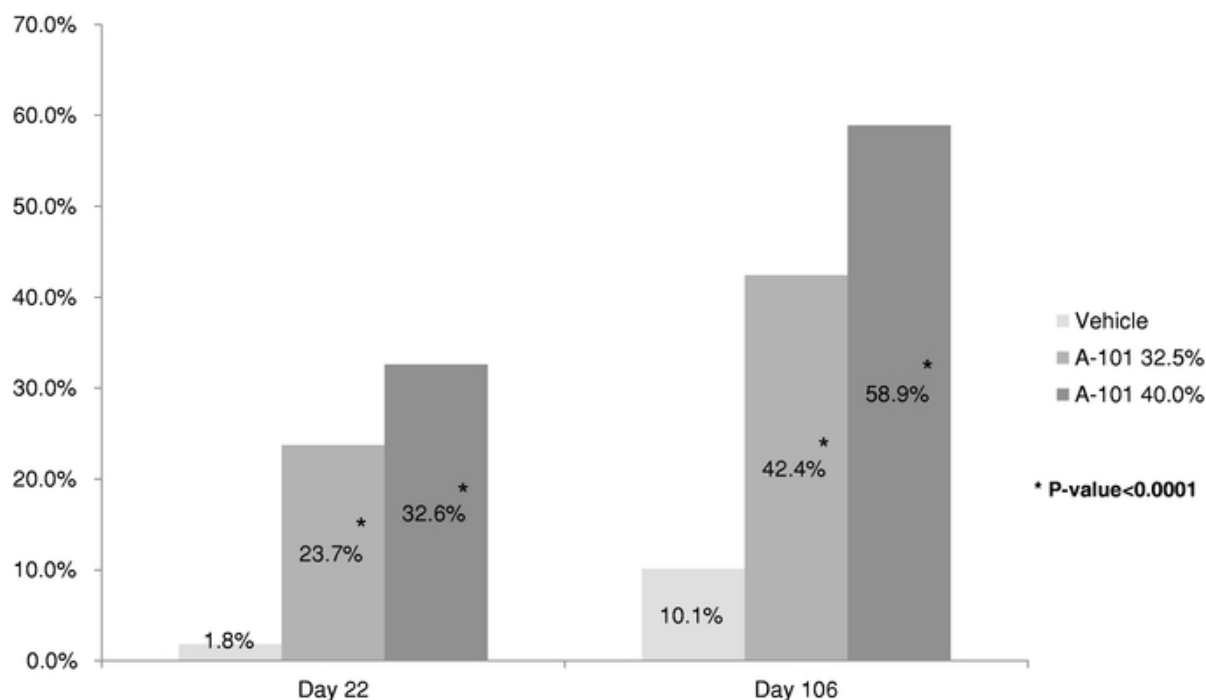
We also measured the percentage of subjects who achieved total clearance, or a PLA score of zero, in all four of their lesions. These results are presented in the table below. Of the subjects receiving A-101 with 40.0% and 32.5% concentrations, 19.6% and 16.1%, respectively, had clearance of all lesions at Day 106, compared to none in the vehicle control group. These results were statistically significant, with a p-value of less than 0.01. At Day 22, 14.3% of the subjects receiving A-101 at the 40.0% concentration had achieved clearance of all lesions, a result that was also statistically significant, with a p-value of less than 0.01. Only 5.4% of subjects receiving A-101 at the 32.5% concentration achieved clearance of all lesions at Day 22, compared to none in the vehicle control group, but this result for the 32.5% group was not statistically significant.

Percentage of Subjects Achieving Total Clearance — Trunk and Extremities



We also measured the percentage of subjects who achieved either total clearance or near clearance, or a PLA score of either zero or one, in all four of their lesions. These results are presented in the table below. At Day 22, 32.6% of the subjects receiving A-101 at the 40.0% concentration achieved total clearance or near clearance and 23.7% of the subjects receiving A-101 at the 32.5% concentration achieved total clearance or near clearance, compared to 1.8% in the vehicle control group. At Day 106, 58.9% of the subjects receiving A-101 at the 40.0% concentration achieved total clearance or near clearance and 42.4% of the subjects receiving A-101 at the 32.5% concentration achieved total clearance or near clearance, compared to 10.1% in the vehicle control group. These results were statistically significant with a p-value of less than 0.0001.

Percentage of Subjects Achieving Total Clearance or Near Clearance — Trunk and Extremities



Safety Results

A-101 was generally well tolerated at both the 32.5% and 40.0% concentrations. Local skin reactions were treatment- and dose-related, and most were considered to be transient and mild to moderate. Treatment-emergent adverse events were reported by 45 subjects. Only one of these events, moderate tenderness at a treatment site on the subject's thigh, was determined by the investigator to be drug-related. Three subjects reported serious adverse events, but none were considered to be related to treatment by the investigator. None of the subjects dropped out of the trial due to adverse events.

Phase 2 Clinical Trial of A-101 in Subjects with Seborrheic Keratosis on the Trunk (Back) (SEBK-201)

Trial Design

We commenced a Phase 2 clinical trial of A-101 in November 2013 that was a double-blind, vehicle-controlled intra-subject clinical trial designed to evaluate the safety, tolerability and initial efficacy of A-101 in clearing SK lesions. The trial compared three active concentrations of A-101, 40.0%, 32.5% and 25.0%, with a vehicle solution control. In the trial, each subject received each of the four treatments on four separate lesions on the back. We enrolled 35 adult subjects in the trial at one site in the United States. We completed the trial in June 2014. Of the 35 subjects enrolled in the trial, one subject withdrew from participation in the trial due to the distance between the subject's home and the clinical trial site. The age of the subjects ranged from 55 to 85, with a mean of 69 years. Of the 35 subjects enrolled in the trial, 20 of the subjects were female and 15 were male, and all subjects were Caucasian. Inclusion criteria included a clinical diagnosis of stable clinically typical SK and at least four appropriate SK target lesions on the subject's back. Exclusion criteria included clinically atypical or rapidly growing SK lesions and the use of specified topical or systemic therapies within a defined time period prior to the first visit.

The evaluation period consisted of 11 weeks after initial treatment. At the first visit, the investigator identified four target lesions on the back for treatment. During a second visit, or baseline, which occurred on Day 1 of the evaluation period, lesions on each subject were randomized to receive the vehicle control or one of the three active concentrations of A-101, and the applications were performed by non-physician

staff. No applications were made at visits on Day 8 and Day 15. On Day 22, any target lesion that met the retreatment criteria received a second application of the assigned concentration of A-101 or vehicle control. No applications were made at subsequent visits, which occurred on Days 29, 43, 57 and 78.

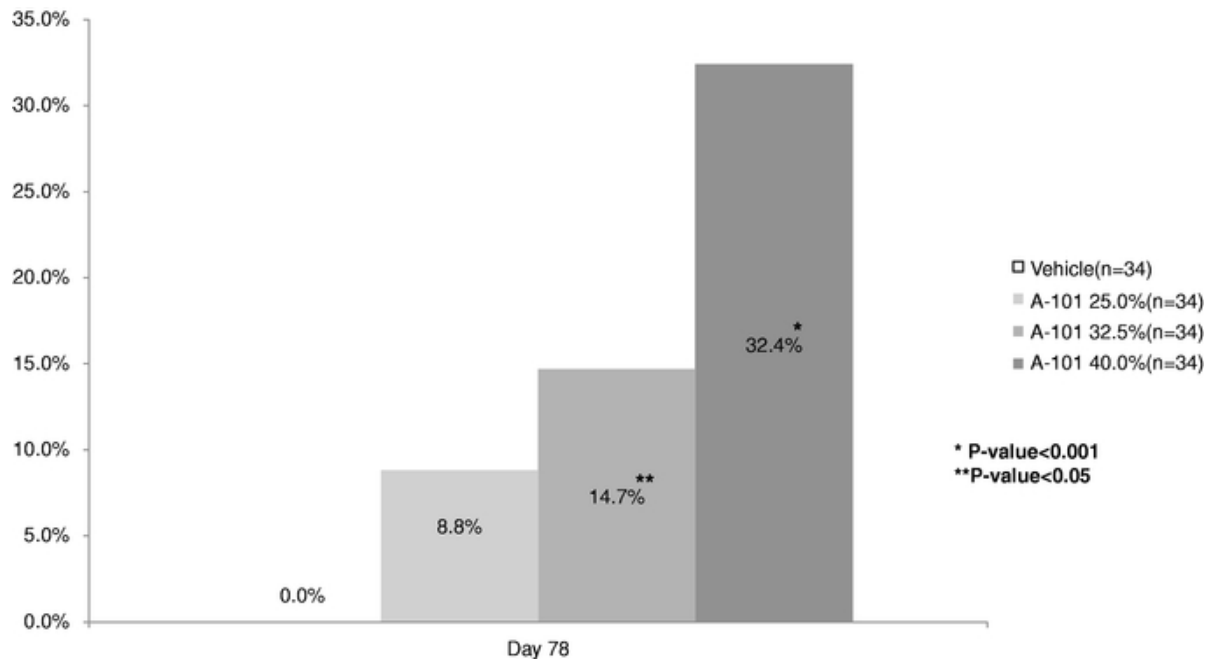
Endpoints

The primary endpoint of this clinical trial was reduction in PLA score from baseline over a period of 78 days, as well the physician's subjective assessment of the condition of the lesion. In this trial, we used an earlier version of the PLA scale in which a PLA score of zero was considered to be complete clearance of the lesion, a PLA score of one represented the lesion was barely evident on examination, a PLA score of two represented an obvious lesion, while a PLA score of three represented a severe, prominent lesion. This PLA scale was subsequently refined in our later trials to make it more clinically objective.

Efficacy Results

For the 34 subjects that completed the trial, the efficacy results are presented in the table below. We measured the proportion of PLA complete responders, defined as a PLA score of zero at Day 78, in each treatment group. Of the 34 lesions treated with the 40.0% concentration, 11 lesions, or 32.4%, completely responded, a result that was statistically significant with a p-value of less than 0.001. Of the 34 lesions treated with the 32.5% concentration, 5 lesions, or 14.7%, completely responded, a result that was statistically significant with a p-value of less than 0.05. Of the 34 lesions treated with the 25.0% concentration, 3 lesions, or 8.8%, completely responded, a result that was not statistically significant. There were no complete responders in the vehicle control group.

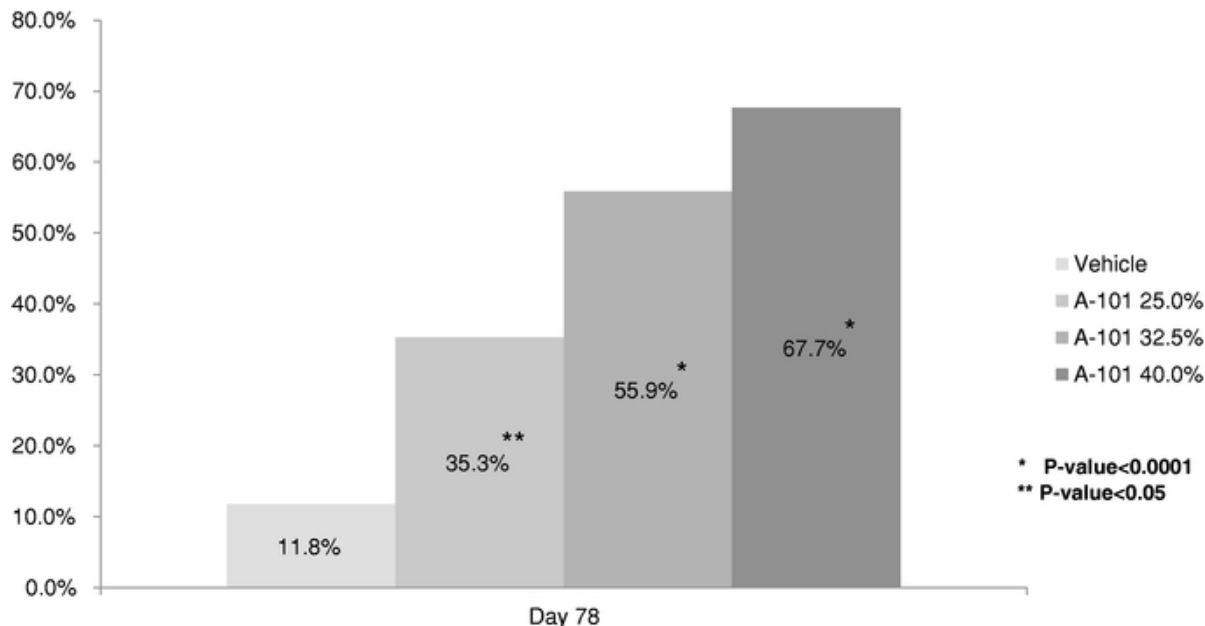
Percentage of Complete Responders — Trunk (Back)



We also measured the proportion of PLA complete responders or near complete responders, defined as a PLA score of zero or one, at Day 78, in each treatment group. These results are presented in the table below. Of the 34 lesions treated with the 40.0% concentration, 23 lesions, or 67.7%, were complete or near complete responders, a result that was statistically significant with a p-value of less than 0.0001. Of the 34 lesions treated with the 32.5% concentration, 19 lesions, or 55.9%, were complete or near complete responders, a result that was statistically significant with a p-value of less than 0.0001. Of the 34 lesions treated with the 25.0% concentration, 12 lesions, or 35.3%, were complete or near complete

responders, a result that was statistically significant with a p-value of less than 0.05. Four lesions, or 11.8%, of the lesions treated with vehicle control either were complete or near complete responders.

Percentage of Complete or Near Complete Responders — Trunk (Back)



Safety Results

A-101 was generally well tolerated at the 25.0%, 32.5% and 40.0% concentrations. Local skin reactions were transient and treatment- and dose-related, and most were considered to be mild to moderate. Treatment-emergent adverse events were reported by nine subjects, and none of those reported were considered to be treatment-related. The only treatment-emergent adverse events reported by more than one subject were seasonal allergy in ten subjects and arthritis in four subjects. One subject had a serious adverse event of kidney infection, which was considered by the investigator to be unrelated to treatment. None of the subjects dropped out of the trial due to an adverse event and no adverse event led to trial discontinuation.

Planned Phase 3 Clinical Program

We held an end-of-Phase 2 meeting with the FDA in May 2015. Based on the FDA's feedback at that meeting, we plan to initiate three Phase 3 clinical trials in the second half of 2015 for the treatment of SK on the face, trunk and extremities. We have also requested scientific advice from the EMA.

Our planned Phase 3 clinical program will consist of three clinical trials, in which we expect to enroll a total of approximately 1,000 subjects with SK. These clinical trials will be designed to demonstrate the efficacy of treatment with A-101 relative to vehicle for the treatment of SK on the face, trunk and extremities. The first two clinical trials will be randomized, multi-center, double-blinded, vehicle-controlled, parallel group Phase 3 clinical trials that will be conducted in the United States. We expect to enroll approximately 400 subjects with four SK lesions on the face, trunk and extremities in each of these two trials. In each of these first two trials, subjects will be randomized to receive A-101 topical solution at the 40.0% concentration on Day 1 and Day 22. Thereafter, we plan to conduct the third Phase 3 clinical trial in which approximately 200 subjects with four SK lesions on the face, trunk and extremities will receive up to four treatments of A-101 21 days apart on an open-label basis in order to gather additional data on the

extended use of A-101. In our three Phase 3 clinical trials, we intend to use the refined PLA scale that we used in our SEBK-202 and SEBK-203 clinical trials.

We anticipate that our NDA for A-101 in SK will be based on the data collected from each of the three Phase 3 clinical trials. We believe that if these results are favorable, such results would be sufficient to support an NDA for the treatment of SK in the United States.

Additional Development Programs — A-101 for Common Warts

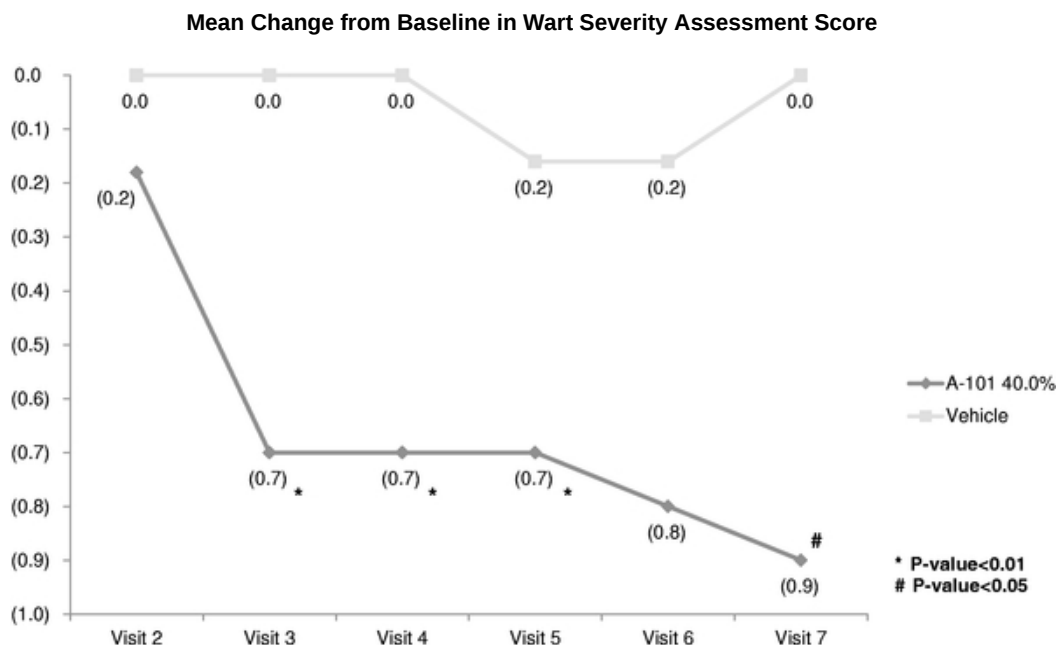
Development Plan

We are conducting toxicology studies and plan to commence Phase 2 clinical trials of A-101 for the treatment of common warts in the second half of 2015.

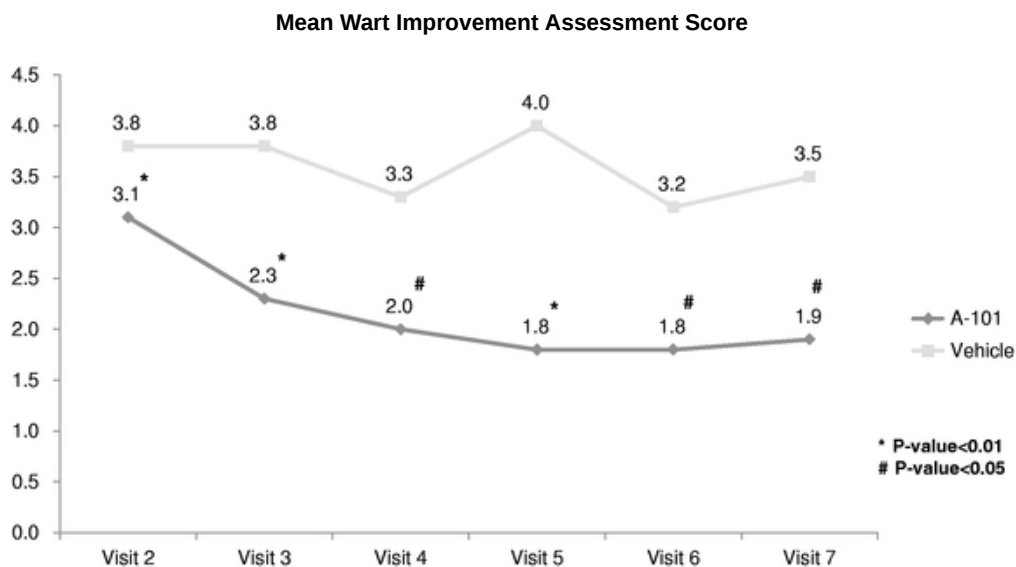
Investigator-Sponsored Trial

A trial was conducted by Steven Grekin, a dermatologist, using A-101 topical solution in subjects with common warts. This physician's IND for the treatment of common warts was submitted to the FDA in March 2014. This trial was a double-blind, vehicle-controlled trial comparing the 40.0% concentration of A-101 and a vehicle control. This trial was conducted at the Grekin Skin Institute in Michigan. In this trial, each subject received four treatments on one target wart. 22 subjects were enrolled in the trial, with 15 subjects completing the trial. Four subjects who were receiving vehicle control did not complete the trial because they were not satisfied with the results and three subjects who were receiving A-101 did not complete the trial for reasons unrelated to treatment. Of the subjects who completed the trial, nine subjects received the 40.0% concentration of A-101 and six subjects received the vehicle control. Subjects were at least 18 years old with a common wart on the hand.

We believe the results of the investigator-sponsored trial provided proof-of-concept data for the treatment of common warts with A-101. Efficacy measures were evaluated at week 6, two weeks after the last treatment. The trial evaluated the mean change from baseline using a wart severity assessment scale ranging from zero to three. A wart severity assessment score of zero means the subject has no clinically diagnosable wart, a score of one means the subject has a barely evident clinically diagnosable wart, a score of two represents an obvious wart and a score of three represents a conspicuous wart. All of the subjects enrolled in this trial had a wart severity assessment score of at least two. The wart severity assessment score results are presented in the table below. The data from the trial showed statistically significant improvements in subjects treated with A-101 compared to vehicle control in the mean wart severity assessment score.



The trial also evaluated the mean wart improvement assessment score in subjects. The wart improvement assessment scale measures the level of improvement and ranges from zero to five. A wart improvement assessment score of zero means the common wart is completely cleared, a score of one means the wart markedly improved compared to baseline, a score of two means the wart moderately improved compared to baseline, a score of three means the wart mildly improved compared to baseline, a score of four means there was no change and a score of five means the wart worsened compared to baseline. The mean wart improvement assessment score results are presented in the table below. The data from the trial showed statistically significant improvements in subjects treated with A-101 compared to vehicle control in the mean wart improvement assessment score.



A-101 was well tolerated in these subjects with no adverse events reported.

In addition, we conducted 12-week toxicology studies in rats and minipigs. These studies were designed to enable us to evaluate a dose range trial over an extended period evaluating two concentrations of A-101 topical solution versus vehicle control in subjects with common warts. Based on these results and those of the investigator-sponsored trial, we are conducting additional toxicology studies and plan to commence Phase 2 clinical trials of A-101 for the treatment of common warts in the second half of 2015.

Manufacturing

We do not have any manufacturing facilities or personnel. We rely on third parties for the manufacture of A-101 for preclinical studies and clinical trials, and will continue to rely on third parties for the commercial manufacture of A-101 if it receives marketing approval. For hydrogen peroxide, the active pharmaceutical ingredient, or API, in A-101, we have entered into an exclusive, ten-year, automatically renewable supply agreement with PeroxyChem LLC, or PeroxyChem, a manufacturer of hydrogen peroxide, to provide the API that can be used in A-101 for the treatment of SK and a number of other specified dermatological indications. We or PeroxyChem may terminate the supply agreement with prior written notice immediately for specified financial reasons, after a 10-day and 60-day cure period for material monetary and non-monetary material breaches, respectively, and in the event of a force majeure event, including if the FDA does not approve A-101 for commercial sale in the United States, that continues for 90 consecutive days. In addition, we may terminate the PeroxyChem supply agreement, with prior written notice, for PeroxyChem's failure to supply API to us for more than 90 cumulative days in a year.

For some of the components used in connection with the manufacture and assembly of the pen-type applicator for A-101, we purchase our components from third-party manufacturers on a purchase order basis and do not have supply arrangements in place. In addition, we have engaged third parties for the supply and assembly of components of the pen-type applicator and the assembly, labeling and packaging of the finished drug product to be used in our planned Phase 3 clinical trials and for commercial purposes, if A-101 is approved for marketing.

Replacement of any of these third-party manufacturers would require us to qualify new manufacturers and negotiate and execute contractual agreements with them. If any of our supply or service agreements with third-party manufacturers are terminated, we will experience delays and additional expenses in the completion of the development of and obtaining regulatory approval for our lead drug candidate, A-101 for the treatment of SK.

Commercialization

For A-101, we expect to retain U.S. commercial rights and to establish collaborations with third parties to commercialize A-101 outside the United States. We have not established any meaningful sales, marketing or product distribution operations to date because A-101 is still in clinical development. We plan to establish the required capabilities within an appropriate time frame ahead of any potential drug approval and commercialization in order to support a commercial product launch. If we commercialize A-101, or any other drug candidates that we may successfully develop, in the United States, we intend to build a targeted sales force to establish relationships with dermatologists. We believe a scientifically oriented, customer-focused team of approximately 45 sales representatives would allow us to reach the approximately 5,000 dermatologists in the United States with the highest potential for using A-101, who we estimate account for over 70% of the procedures performed. We expect that our sales force will be supported by sales and marketing management, internal sales and marketing support and commercial product distribution support.

In a survey we commissioned in 2014, dermatologists who were presented the product profile for A-101 reacted favorably. Among 251 dermatologists who completed the survey, 85% indicated that they "definitely would" or "probably would" treat their patients with A-101. In addition, 77% said A-101 "improves treatment options extremely well" or "improves treatment options very well" for SK. Some of the dermatologists who completed the survey noted A-101 would be a good alternative to cryosurgery, could be

utilized in patients that are not candidates for cryosurgery, such as darker-skinned patients and patients with numerous lesions, and could help grow practice revenue.

We believe dermatologists will be inclined to adopt A-101 to treat their patients with SK, if it is approved, not only because of its clinical profile, but also because it may provide an expanded source of revenue for their practices. Dermatologists expect declining reimbursements from third-party payors for providing medical services. In addition, a greater portion of the cost of medical care has been shifted to patients, in the form of higher deductibles and co-insurance. Collecting from patients can be difficult and costly for physician practices. We believe many dermatologists are interested in expanding the cash-pay aesthetic portion of their practices, meaning the portion of procedures that are not medically necessary and not reimbursed by third-party payors, by treating new aesthetic patients and by offering new services to current aesthetic patients. Though SK patients typically come into the dermatology practice seeking a medical diagnosis, we believe they often are willing to pay for removal of SK lesions to improve appearance even after they learn that the lesions are non-malignant and that removal may not be reimbursed. We expect the cost to patients for A-101, if approved, to be lower than many of the other minimally invasive cash-pay aesthetic procedures offered by dermatologists, such as dermal fillers, neuromodulators, laser hair removal, and intense pulsed light treatments. In addition, since A-101 can be administered by non-physician staff, we believe it could provide incremental practice revenue with minimal time commitment by the dermatologist after the diagnosis is made.

In 2014, there were approximately 10,000 dermatologists practicing in the United States. We believe dermatologists tend to be particularly focused on the safety of pharmaceutical products because, while skin diseases can have profound effects on patients' quality of life, few are life-threatening. As a result, we believe that dermatologists, as well as their patients, often prefer to use topical treatments when possible to limit the risk of systemic side effects. Dermatologists also tend to place a high level of emphasis on products that are easy to use because they often manage high volumes of patients. We believe this also contributes to a general preference for topical treatments. Finally, in our experience, dermatologists tend to engage with sales and medical affairs personnel from the pharmaceutical industry regarding the scientific evidence supporting dermatology products and the challenges experienced by physicians and patients in the use of these products. Dermatologists often rely on trusted relationships with scientifically oriented, customer-focused sales representatives who can provide them with the necessary information to support their use of appropriate treatments.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. While we believe that our knowledge, experience and scientific resources provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical and specialty pharmaceutical companies, academic institutions and governmental agencies and public and private research institutions. Any drug candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future.

The key competitive factors affecting the success of A-101, if approved for the treatment of SK, are likely to be its efficacy, safety, non-invasiveness, pain profile and ability to be administered by non-physician staff.

With respect to A-101 for the treatment of SK, we are aware of one biopharmaceutical company, BioLineRx Ltd., that is developing a combination drug candidate that targets SK, and another company, Skincential Sciences, Inc., that currently markets a line of cosmetic products targeting skin conditions, including SK. Neither of these products have been approved by the FDA for use in the United States.

With respect to A-101 for the treatment of common warts, we are aware of one company, Nielsen BioSciences, that is developing a prescription treatment for common warts. We are aware of another company, G&E Herbal Biotechnology Co., LTD, that intends to initiate a Phase 2 clinical trial of a gel as a prescription treatment for 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 A-101 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. 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 testing, conducting clinical trials, 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 subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

Intellectual Property

Our success depends in large part upon our ability to obtain and maintain proprietary protection for our drug candidates and to operate without infringing the proprietary rights of others. We seek to avoid the latter by monitoring patents and publications that may affect our business, and to the extent we identify such developments, evaluate and take appropriate courses of action. Our policy is to protect our proprietary position by, among other methods, filing for patent applications on inventions that are important to the development and conduct of our business with the U.S. Patent and Trademark Office, or USPTO, and its foreign counterparts.

We have two issued U.S. patents, one issued patent in each of Australia, Germany, United Kingdom, India, New Zealand, Mexico, and Singapore, and two pending U.S. provisional patent applications. We do not currently rely on licenses to any third party's intellectual property. The two U.S. patents include claims that cover the use of high-concentration hydrogen peroxide for the alleviation of SK and acrochordons, and the seven foreign patents include claims that cover the use of high-concentration hydrogen peroxide for the alleviation of various skin conditions, including SK, acrochordons, corns, tags, acne, warts and rosacea. The issued patents begin to expire in 2022, subject to any applicable patent term adjustment or extension that may be available.

Our two pending U.S. provisional patent applications are directed to various formulations comprising high-concentration hydrogen peroxide, dosing regimens for such formulations, applicators for use with such formulations, and methods of treating various skin conditions, including SK and common warts, by the topical administration of such formulations. We plan to pursue these applications by formally filing in the United States and internationally, including in the European Union. Any claims that issue from these formal filings will naturally expire in 2035, subject to any applicable patent term adjustment or extension that may be available.

We also use other forms of protection, such as trademark, copyright, and trade secret protection, to protect our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable. We aim to take advantage of all of the intellectual property rights that are available to us and believe that

this comprehensive approach will provide us with proprietary positions for our drug candidates, where available.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country. In most countries in which we file, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent term may be shortened if a patent is terminally disclaimed over another patent or as a result of delays in patent prosecution by the patentee, and a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent or by patent term extension, which compensates a patentee for delays at the FDA. The patent term of a European patent is 20 years from its filing date; however, unlike in the United States, the European patent does not grant patent term adjustments. The European Union does have a compensation program similar to patent term extension called supplementary patent certificate that would effectively extend patent protection for up to five years.

We also protect our proprietary information by requiring our employees, consultants, contractors and other advisors to execute nondisclosure and assignment of invention agreements upon commencement of their respective employment or engagement. Agreements with our employees also prevent them from bringing the proprietary rights of third parties to us. In addition, we also require confidentiality or service agreements from third parties that receive our confidential information or materials.

Assignment Agreement and Finder's Services Agreement

In August 2012, we entered into an assignment agreement with the Estate of Mickey Miller, or the Miller Estate, under which we acquired some of the intellectual property rights covering A-101. The assignment of intellectual property rights covers specified know-how, along with modifications of, improvements to and variations on A-101 that meet defined chemical properties. Under the agreement, we have the sole and exclusive right, but not the duty, to develop, obtain regulatory approval for and commercialize A-101 worldwide. We are required to use commercially reasonable efforts to develop and commercialize at least one product for at least one indication in the United States. In connection with obtaining the assignment of the intellectual property from the Miller Estate, we also entered into a separate finder's services agreement with KPT Consulting, LLC.

Under the terms of the assignment agreement and the finder's services agreement, we made aggregate upfront payments of \$0.6 million in 2012 and one-time milestone payments of \$0.4 million in 2013 upon the dosing of the first human subject with A-101 in our Phase 2 clinical trial. There are no remaining potential milestone payments under the assignment agreement. Under the finder's services agreement, we are obligated to make additional milestone payments of up to \$1.3 million in the aggregate upon the achievement of specified development and regulatory milestones and up to \$4.5 million upon the achievement of specified commercial milestones. Under each of the assignment agreement and the finder's services agreement, we are also obligated to pay royalties on sales of A-101 or related products, at low single-digit percentages of net sales, subject to reduction in specified circumstances. We have not made any royalty payments to date under either agreement. Both agreements will terminate upon the expiration of the last pending, viable patent claim of the patents acquired under the assignment agreement, but no sooner than 15 years from the effective date of the agreements.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, and analogous authorities in other countries extensively regulate, among other things, the research, development, testing, manufacture, safety surveillance, efficacy, quality control, labeling, packaging, distribution, record keeping, promotion, storage, advertising, distribution, marketing, sale, export and import, and the reporting of safety

and other post-market information of products such as the one we are developing. A drug candidate, such as A-101, must be approved by the FDA before it may be legally promoted in the United States and by comparable foreign regulatory authorities before marketing in other jurisdictions. A-101 and any future drug candidates we may develop will be subject to similar requirements in other countries outside of the European Union and the United States prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by regulatory authorities to approve applications, withdrawal of an approval, imposition of a clinical hold, import/export delays, issuance of warning letters and untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice or other governmental entities.

United States Government Regulation

NDA Approval Processes

In the United States, the FDA regulates drug and medical device products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. Our drug candidates are comprised of both a drug component (the hydrogen peroxide solution or gel) and a pen-type applicator. In the case of our drug candidates, the FDA's Center for Drug Evaluation and Research has primary jurisdiction over the premarket development, review and approval of our drug candidates. Accordingly, we are investigating our drug candidates pursuant to IND applications and expect to seek approval through the NDA pathway. Based on our discussions with the FDA to date, we do not anticipate that the FDA will require us to submit a separate marketing application for the pen-type applicator that will be used with our drug candidates, but this could change during the course of the FDA's review of our NDA.

An applicant seeking approval to market and distribute a new drug product in the United States must typically undertake the following:

- § completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice regulations;
- § submission to the FDA of an IND which must take effect before clinical trials may begin;
- § approval by an independent institutional review board, or IRB, representing each clinical site before clinical testing may be initiated at the clinical site;
- § performance of adequate and well-controlled clinical trials in accordance with good clinical practice, or GCP, regulations to establish the safety and efficacy of the proposed drug product for each indication;
- § preparation and submission to the FDA of a NDA;
- § review of the NDA by a FDA advisory committee, if applicable;
- § satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product or its components are produced to assess compliance with current good manufacturing practices, or cGMP, regulations to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality and purity;
- § payment of user fees and securing FDA approval of the NDA; and
- § compliance with any post-approval requirements, including potential requirements for a risk evaluation and mitigation strategy and post-approval studies required by the FDA.

Once a drug candidate is identified for development, it enters the preclinical or nonclinical testing stage. Preclinical studies include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the preclinical studies, together with manufacturing information and analytical data, to the FDA as part of the IND. Some preclinical studies may continue even after the IND is submitted. In addition to including the results of the preclinical studies, the

IND will also include a protocol detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND, and may affect one or more specific clinical trials or all clinical trials conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with current Good Clinical Practices regulations. They must be conducted under protocols detailing the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol before the clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- § **Phase 1.** The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some products for severe or life-threatening diseases, such as cancer, and especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients who already have the condition.
- § **Phase 2.** Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- § **Phase 3.** If a drug candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 clinical trials, the clinical trial program will be expanded to Phase 3 clinical trials to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These studies are intended to establish the overall risk-benefit ratio of the product and provide an adequate basis for product approval and labeling claims.

Phase 4 clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in withdrawal of approval.

Clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, which is called the clinical monitoring board or data safety monitoring board. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to the submission of an IND, at the end-of-Phase 2 and before a NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end-of-Phase 2 to discuss their Phase 2 clinical trial results and present their plans for the pivotal Phase 3 clinical trial or trials that they believe will support the approval of the new drug.

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

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of a NDA requesting approval to market the product. The submission of a NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. The FDA reviews all NDAs submitted for a period of 60 days to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept a NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

During the approval process, the FDA also will determine whether a risk evaluation and mitigation strategy, or REMS, is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the application must submit a proposed REMS, and the FDA will not approve the application without an approved REMS, if required. A REMS can substantially increase the costs of obtaining approval. The FDA could also require a special warning, known as a boxed warning, to be included in the product label in order to highlight a particular safety risk.

Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA reviews a NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on the NDA from ten months to six months from FDA filing of the NDA. After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval.

Post-approval Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA and other governmental agencies, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. There also are continuing, annual user fee requirements for products and the establishments at which such products are manufactured, as well as new application fees for certain supplemental applications. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with GMP regulations and other laws. The FDA has promulgated specific requirements for drug cGMPs and device cGMPs embodied in the Quality System Regulation. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP requirements and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Failure to comply with the applicable United States requirements at any time during the product development process or approval process, or after approval, may subject us to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- § refusal to approve pending applications;
- § withdrawal of an approval;
- § imposition of a clinical hold;
- § warning letters;
- § product seizures or detention, or refusal to permit the import or export of products;
- § restrictions on the marketing or manufacturing of the product;
- § total or partial suspension of production or distribution or product recalls; or
- § injunctions, fines, disgorgement, or civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of drug products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often issued revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be issued or changed or what the impact of such changes, if any, may be.

Non-patent Exclusivity

The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. Because we believe that an NDA has never been approved for hydrogen peroxide, we believe that our product qualifies as a new chemical entity and is entitled to a five year period of market exclusivity under the FDCA if approved, but FDA may disagree with our interpretation.

If market exclusivity is granted, during the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to regulations of other countries governing our business activities, including, our clinical trials and the commercial sale and distribution of our product. Even if we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, or EU, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing and promotion, pricing and reimbursement vary greatly by geographic region, and the time may be longer or shorter than that required for FDA approval.

Under EU regulatory systems, a company may submit a Market Authorization Application, or MAA, either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all EU member states. The decentralized procedure provides for mutual recognition of national approval decisions. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Marketing exclusivities are also available in the European Union and certain other foreign jurisdictions. For example, in the European Union, the EMA is prohibited from approving an MAA for ten years from first approval of the reference product. We intend to rely on any available marketing exclusivity for A-101 with respect to potential commercialization in Europe.

Other Healthcare Laws

Although we currently do not have any products on the market we are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign

jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, physician sunshine and privacy and security laws.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Violations of this law are punishable by up to five years in prison, and can also result in criminal fines, civil money penalties, administrative penalties and exclusion from participation in federal healthcare programs.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, or for providing medically unnecessary services or items. In addition, our future activities relating to the sale and marketing of our product are subject to scrutiny under this law. Penalties for the federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between \$5,500 and \$11,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act imposed, among other things, new annual reporting requirements for covered manufacturers for certain payments and other transfers of value provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year and up to an aggregate of \$1 million per year for "knowing failures." Covered manufacturers must submit reports to the Centers for Medicare and Medicaid Services by the 90th day of each calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

Because we intend to commercialize a product that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs designed to establish internal controls and facilitate compliance can mitigate the risk of investigation, prosecution, and penalties assessed for violations of these laws, or any other laws that may apply to us, the risks cannot be entirely eliminated. If our operations are found to be in violation of any of such laws or any other governmental regulations, we may be subject to penalties, including, without limitation, administrative, civil, and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to "business associates", namely independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

Health Care Reform

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act was passed, which has had, and is expected to continue to have, a significant impact on the healthcare industry. The Affordable Care Act was designed to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the Affordable Care Act expanded and increased industry rebates for drugs covered under Medicaid programs; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the rebate program to individuals enrolled in Medicaid managed care organizations; established annual fees and taxes on manufacturers of certain branded prescription drugs; and made changes to the coverage requirements under the Medicare prescription drug benefit; and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Moreover, the Affordable Care Act provided incentives to programs that increase the federal government's comparative effectiveness research and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. We continue to evaluate the effect that the Affordable Care Act will have on our business. In the coming years, additional legislative and regulatory changes could be made to governmental health programs that could significantly impact pharmaceutical companies and the success of our drug candidates.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect beginning on April 1, 2013 and, due to subsequent legislative amendments to the statute, will stay in effect through 2024 unless additional Congressional action is taken. Additionally, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, cancer treatment centers and imaging centers. Moreover, the Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products related to product tracking and tracing. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products.

The Affordable Care Act, as well as other federal and state healthcare reform measures that have been and may be adopted in the future, could harm our future revenue. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

The Hatch Waxman Amendments to the FDC Act

Orange Book Listing

In seeking approval for a drug through a NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product or a method of using the product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA or an application covered by Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, or FDCA. An ANDA provides for marketing of a drug product that has the same active ingredients, generally in the same strengths and dosage form, as the listed drug and has been shown through pharmacokinetic, or PK, testing to be

bioequivalent to the listed drug. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are generally not required to conduct, or submit results of, preclinical studies or clinical tests to prove the safety or effectiveness of their drug product. Section 505(b)(2) applications provide for marketing of a drug product that may have the same active ingredients as the listed drug and contains full safety and effectiveness data as a NDA, but at least some of this information comes from studies not conducted by or for the applicant. This alternate regulatory pathway enables the applicant to rely, in part, on the FDA's findings of safety and efficacy for an existing product, or published literature, in support of its application. The FDA may then approve the new drug candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

The ANDA or Section 505(b)(2) applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA or Section 505(b)(2) applicant may also elect to submit a statement certifying that its proposed ANDA label does not contain, or carves out, any language regarding a patented method of use rather than certify to such listed method of use patent. If the applicant does not challenge the listed patents by filing a certification that the listed patent is invalid or will not be infringed by the new product, the ANDA or Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired.

A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA or Section 505(b)(2) applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA or Section 505(b)(2) application has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or Section 505(b)(2) application until the earliest of 30 months, expiration of the patent, settlement of the lawsuit, and a decision in the infringement case that is favorable to the ANDA or Section 505(b)(2) applicant. This prohibition is generally referred to as the 30-month stay. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor's decision to initiate patent litigation.

The ANDA or Section 505(b)(2) application also will not be approved until any applicable non patent exclusivity listed in the Orange Book for the referenced product has expired.

We intend to list any patents that are eligible for listing in the Orange Book in our NDA.

Patent Term Extension

In the United States, after NDA approval, owners of relevant drug patents may apply for up to a five year patent extension, which provides patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The allowable patent term extension is calculated as half of the drug's testing phase, which is the time between the IND submission becoming effective and the NDA submission, and all of the review phase, which is the time between NDA submission and approval, up to a maximum extension of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended.

Similar provisions are available in the European Union and other foreign jurisdictions to extend the term of a patent that covers an approved drug. For example, in Japan, it may be possible to extend the patent term for up to five years and in the European Union, it may be possible to obtain a supplementary patent certificate that would effectively extend patent protection for up to five years. In the future, if our drug candidates receive FDA approval, we expect to apply for patent term extensions on patents covering those drugs.

Coverage and Reimbursement

We do not expect third-party payors to cover and reimburse customers who use A-101 or A-102 on patients for the treatment of SK. Payors generally do not reimburse the provider for the product used to remove non-malignant lesions, including SK. In addition, they do not generally reimburse providers for the procedure removing such lesions, since the procedure is considered to be cosmetic in nature, unless there is a medical need to remove the lesion such as confirming a diagnosis with a biopsy or treating SK that are causing the patient physical discomfort. We anticipate that in some cases, our drug candidates will be used to remove SK lesions that are inflamed and causing the patient discomfort. Any reduction in reimbursement for the procedure to remove inflamed SK may result in a higher percentage of patients needing to pay out of pocket for treatment with our drug candidates. Accordingly, the commercial success with A-101 and A-102 depends on the extent to which patients will be willing to pay out of pocket for the in-office procedure using these drug candidates.

By contrast, in the case of A-101 and A-102 for the treatment of common warts, we believe our success depends on continued coverage and adequate reimbursement for in-office wart treatment procedures or in the absence of coverage and adequate reimbursement, on the extent to which patients will be willing to pay out of pocket for the in-office procedures that include our product.

Third-party payors determine which medical procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure and may be unwilling to undergo such procedures for the removal of warts in the absence of such coverage and reimbursement. Physicians may be unlikely to offer procedures for the treatment of warts if they are not covered by insurance and may be unlikely to purchase and use our product for warts unless coverage is provided and reimbursement is adequate.

Reimbursement by a third-party payor may depend upon a number of factors, including: the third-party payor's determination that a procedure is neither cosmetic, experimental, nor investigational; safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; and included in clinical practice guidelines.

In the United States, no uniform policy of coverage and reimbursement for medical procedures exists among third-party payors. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor. Decisions regarding the extent of coverage and amount of reimbursement to be provided for an in-office procedure to remove warts are made on a plan by plan basis. One payor's determination to provide coverage for a procedure does not assure that other payors will also provide coverage, and adequate reimbursement.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes annual updates to payments to physicians for procedures during which our drug candidates will be used. To the extent the procedure using our drug candidates would be covered, the cost of our drugs generally is recovered by the healthcare provider as part of the payment for performing a procedure and not separately reimbursed. Accordingly, these updates could impact the demand for our drug candidates. An example of payment updates is the Medicare program's updates to hospital and physician payments, which are done on an annual basis using a

prescribed statutory formula. In the past, when the application of the formula resulted in lower payment, Congress has passed interim legislation to prevent the reductions. Most recently, the Protecting Access to Medicare Act of 2014, signed into law in April 2014, provided for a 0.5% update from 2013 payment rates under the Medicare Physician Fee Schedule through 2014 and a 0% update from January 1 until March 31, 2015. If Congress fails to intervene to prevent the negative update factor in future years, we could face a decline in revenue to the extent any of our drug candidates receive regulatory approval and procedures using these drug candidates are covered for reimbursement.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our drugs are used under any foreign reimbursement system.

Employees

As of March 31, 2015, we had ten employees. All of our employees are located in the United States. None of our employees is represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Properties

We sublease 4,833 square feet of space for our headquarters in Malvern, Pennsylvania under a sublease with a term through November 30, 2016, subject to renewal for at least two six-month terms. We sublease this space from an entity affiliated with some of our executive officers and directors. See "Certain Relationships and Related Party Transactions — Subleases" for a description of the terms of this sublease. We believe that our current facilities are suitable and adequate to meet our current needs. We intend to add new facilities or expand existing facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

We are not subject to any material legal proceedings.

MANAGEMENT**Directors and Executive Officers**

The following table sets forth information concerning our directors and executive officers, including their ages as of January 31, 2015:

Name	Age	Position
Executive Officers:		
Neal Walker	45	President, Chief Executive Officer and Director
Christopher Powala ⁽¹⁾	55	Chief Operating Officer
Stuart Shanler, M.D. ⁽¹⁾	53	Chief Scientific Officer
Kamil Ali-Jackson ⁽¹⁾	55	Chief Legal Officer
Frank Ruffo ⁽¹⁾	49	Chief Financial Officer
Non-Management Directors:		
Stephen A. Tullman	49	Chairman of the Board of Directors
Albert Cha, M.D., Ph.D.	42	Director
Anand Mehra, M.D.	39	Director
Christopher Molineaux	49	Director
Ketan Patel, M.D.	39	Director

⁽¹⁾ This executive officer provides part-time services to another company under common control with us. Under a services agreement with NST Consulting, LLC, we are reimbursed by NST Consulting, LLC for the services provided by the executive officer to the other company. See "Certain Relationships and Related Party Transactions — Services Agreements with Ceptaris and NST" for additional information.

Executive Officers**Neal Walker**

Neal Walker co-founded our company and has served as President and Chief Executive Officer and a member of our board of directors since our inception in July 2012. Dr. Walker co-founded NeXeption, LLC, a biopharmaceutical assets management company, in August 2012. Between July 2011 and July 2012, Dr. Walker served as a consultant to a number of pharmaceutical companies. Dr. Walker co-founded and served as President and Chief Executive Officer and a member of the board of directors of Vicept Therapeutics, Inc., a dermatology-focused specialty pharmaceutical company, from 2009 until its acquisition by Allergan, Inc. in July 2011. Previously, Dr. Walker co-founded and led a number of life science companies, including Octagon Research Solutions, Inc., a software and services provider to biopharmaceutical companies (acquired by Accenture plc), Trigenesis Therapeutics, Inc., a specialty dermatology company, where he served as Chief Medical Officer (acquired by Dr. Reddy's Laboratories Inc.), and Cutix Inc., a commercial dermatology company. He began his pharmaceutical industry career at Johnson and Johnson, Inc. Dr. Walker is a director of Alderya Therapeutics, Inc, a publicly held biotechnology company, as well as several private biotechnology companies. Dr. Walker received his M.B.A. degree from The Wharton School, University of Pennsylvania, his Doctor of Osteopathic Medicine degree from the Philadelphia College of Osteopathic Medicine and a B.A. degree in Biology from Lehigh University. Dr. Walker's experience as a board-certified dermatologist and the founder of our company and other pharmaceutical companies, his background in clinical and product development in dermatology and other fields, and his knowledge of the pharmaceutical industry contributed to the conclusion of our board of directors that he should serve as a director of our company.

Christopher Powala

Christopher Powala co-founded our company and has served as our Chief Operating Officer since our inception in July 2012. Between July 2011 and July 2012, Mr. Powala served as a consultant to a number

of pharmaceutical companies. Mr. Powala co-founded and served as Chief Operating Officer of Vicept Therapeutics, Inc. from 2009 until its acquisition by Allergan, Inc. in July 2011. Prior to joining Vicept Therapeutics, Inc., from 2008 to 2009, he served as Vice President, Clinical Operations & Global Regulatory Affairs for Vital Therapies, Inc., a biotechnology company. From 1993 to 2008, Mr. Powala was with CollaGenex Pharmaceuticals, Inc, a dermatology-focused specialty pharmaceutical company, where he served as Vice President, Drug Development and Regulatory Affairs. Previously, Mr. Powala also held various positions in product development and regulatory affairs at Wyeth Laboratories, Inc. Mr. Powala received his bachelor's degree in Biology from State University of New York-Regents College.

Stuart D. Shanler, M.D.

Stuart D. Shanler, M.D. co-founded our company and has served as our Chief Scientific Officer since our inception in July 2012. Between July 2011 and July 2012, Dr. Shanler served as a consultant to a number of pharmaceutical companies. Dr. Shanler co-invented a topical rosacea drug for, and co-founded and served as Chief Scientific Officer of, Vicept Therapeutics, Inc. from 2009 until its acquisition by Allergan, Inc. in July 2011. Previously, Dr. Shanler was a dermatologic surgeon in private practice. Dr. Shanler is a board-certified dermatologist and received his M.D. degree from Albany Medical College of Union University and received B.S. degrees in Biology and the Biological Basis of Behavior from the University of Pennsylvania.

Kamil Ali-Jackson

Kamil Ali-Jackson co-founded our company and has served as our Chief Legal Officer and Assistant Secretary since our inception in July 2012. In addition, since May 2011, Ms. Ali-Jackson has served as the Chief Legal Officer of NeXeption, Inc. and its affiliates, and has served as the Chief Legal Officer of Alexar Therapeutics, Inc. since January 2014. From May 2011 to September 2013, Ms. Ali-Jackson served as Chief Legal Officer, Chief Compliance Officer and Secretary of Ceptaris Therapeutics, Inc., a biotechnology company. From October 2010 to September 2011, she was a consultant to a private biopharmaceutical company. From 2006 to May 2010, she served as General Counsel and Corporate Secretary of Ception Therapeutics, Inc., a biotechnology company that was acquired by Cephalon, Inc. Previously, Ms. Ali-Jackson served as a legal officer and licensing business executive for a number of pharmaceutical companies, including Merck & Co., Inc., Dr. Reddy's Laboratories Inc. and Endo Pharmaceuticals, Inc. Ms. Ali-Jackson received her J.D. degree from Harvard Law School and A.B. degree in Politics from Princeton University.

Frank Ruffo

Frank Ruffo co-founded our company and has served as our Chief Financial Officer and Secretary since our inception in July 2012. Mr. Ruffo also served part-time as the Chief Financial Officer of VenatoRx Pharmaceuticals Inc., a pharmaceutical company, from October 2011 to November 2014 and the Chief Financial Officer of BioLeap, Inc. from January 2010 to January 2013. Prior to joining our company, Mr. Ruffo co-founded and served as Chief Financial Officer of Vicept Therapeutics, Inc. from 2009 until its acquisition by Allergan, Inc. in July 2011. Prior to joining Vicept Therapeutics, Inc., from 1996 to 2008, Mr. Ruffo served as the Vice President, Finance and Controller of CollaGenex Pharmaceuticals, Inc. Mr. Ruffo received a B.S. degree in Accounting from LaSalle University.

Non-Management Directors

Stephen A. Tullman

Stephen A. Tullman has served as Chairman of our board of directors since August 2012. Mr. Tullman co-founded NeXeption, Inc. in May 2011 and NeXeption, LLC in August 2012 and currently serves as the managing member of NeXeption, LLC. He previously served as Chairman, President and Chief Executive Officer of Ceptaris Therapeutics, Inc., a biopharmaceutical company, from May 2011 until its acquisition by Actelion US Holdings Company, a subsidiary of Actelion Ltd, in September 2013. Mr. Tullman co-founded Vicept Therapeutics, Inc. and served as its Chairman from 2009 until its acquisition by Allergan, Inc. in July 2011. In 2005, Mr. Tullman co-founded Ception Therapeutics, Inc. and served as its President and

Chief Executive Officer until its acquisition by Cephalon, Inc. in 2010. In 2003, Mr. Tullman co-founded Trigenesis Therapeutics, Inc., where he served as its Chief Business Officer (acquired by Dr. Reddy's Laboratories Inc.) Mr. Tullman began his career at SmithKline Beecham, a pharmaceutical company, where he held positions of increasing responsibility in finance, sales, marketing, and research and development. Mr. Tullman currently serves as the chairman of the board of directors of Alexar Therapeutics, Inc., a specialty dermatology company, and on the boards of directors of several other privately held companies. Mr. Tullman received a B.S. degree in Accounting from Rutgers University. Our board of directors believes that Mr. Tullman's leadership, executive, managerial and business experience with several life sciences companies qualify him to serve as a director of our company.

Albert Cha, M.D., Ph.D.

Albert Cha, M.D., Ph.D. has served as a member of our board of directors since August 2012. In 2000, Dr. Cha joined Vivo Capital, a healthcare investment firm, where he has served in various positions, and he currently serves as a managing partner. Dr. Cha currently serves as a member of the boards of directors of several privately held biotechnology and medical device companies. Dr. Cha holds B.S. and M.S. degrees in Electrical Engineering from Stanford University and an M.D. degree and Ph.D. degree in Neuroscience from the University of California at Los Angeles. Our board of directors believes that Dr. Cha's substantial experience with companies in the healthcare sector and his financial and business experience qualify him to serve as a director of our company.

Anand Mehra, M.D.

Anand Mehra, M.D. has served as a member of our board of directors since September 2014. Dr. Mehra joined Sofinnova Ventures, a venture capital firm, in 2007 and currently serves as a general partner. Prior to joining Sofinnova, Dr. Mehra worked in J.P. Morgan's private equity and venture capital group, and before that, Dr. Mehra was a consultant in McKinsey & Company's pharmaceutical practice. Dr. Mehra currently serves on the boards of directors of the publicly held companies Spark Therapeutics, Inc., Aerie Pharmaceuticals, Inc. and Marinus Pharmaceuticals, Inc., as well as several private companies. Dr. Mehra received his B.A. degree in political philosophy from the University of Virginia and an M.D. degree from Columbia University's College of Physicians and Surgeons. Our board of directors believes that Dr. Mehra is qualified to serve on our board of directors because of his extensive experience in the life sciences industry, his service on the boards of directors of other public life sciences companies and his extensive leadership experience.

Christopher Molineaux

Christopher Molineaux has served as a member of our board of directors since January 2014. Since 2009, Mr. Molineaux has served as President and Chief Executive Officer of Pennsylvania BIO, a pharmaceutical and biotech industry advocacy organization. Prior to joining Pennsylvania BIO, Mr. Molineaux served as worldwide Vice President of pharmaceutical communication and public affairs for Johnson & Johnson. Mr. Molineaux previously served as Vice President for Public Affairs at the Pharmaceutical Research and Manufacturers Association. He holds a B.A. degree from the College of the Holy Cross. Our board of directors believes that Mr. Molineaux's substantial pharmaceutical and biotechnology industry experience qualifies him to serve as a director of our company.

Ketan Patel, M.D.

Ketan Patel, M.D. has served as a member of our board of directors since August 2012. In 2007, Dr. Patel joined Fidelity Biosciences, an investment firm, where he currently serves as principal. Previously, he was an engagement manager in the MEDACorp consulting division of Leerink Swann & Company. Prior to this, Dr. Patel was a physician at the Weill-Cornell Medical Center of New York Presbyterian Hospital and at the Memorial Sloan Kettering Cancer Center. He received his B.A. degree in biology and economics at Rutgers University and his M.D. degree from Tufts University School of Medicine. Our board of directors believes that Dr. Patel's substantial experience with companies in the healthcare sector and his venture capital, financial and business experience qualify him to serve as a director of our company.

Board Composition

Our board of directors currently consists of six members. Mr. Tullman is the chairman of our board of directors. Each director is currently elected to the board for a one-year term, to serve until the election and qualification of successor directors at the annual meeting of stockholders, or until the director's earlier removal, resignation or death.

Our directors were elected to and currently serve on the board pursuant to a voting agreement among us and several of our largest stockholders. This agreement will terminate upon the closing of this offering, after which there will be no further contractual obligations regarding the election of our directors.

In accordance with our amended and restated certificate of incorporation, which will be in effect upon the closing of this offering, our board of directors will be divided into three classes, each of which will consist, as nearly as possible, of one-third of the total number of directors constituting our entire board and which will serve staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- § Class I, which will consist of _____ and _____, and their term will expire at our first annual meeting of stockholders to be held after the closing of this offering;
- § Class II, which will consist of _____ and _____, and their term will expire at our second annual meeting of stockholders to be held after the closing of this offering; and
- § Class III, which will consist of _____ and _____, and their term will expire at our third annual meeting of stockholders to be held after the closing of this offering.

Our amended and restated bylaws, which will become effective upon the closing of this offering, will provide that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors.

The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control.

Director Independence

Our board of directors has undertaken a review of the independence of the directors and considered whether any director has a material relationship with us that could compromise his ability to exercise independent judgment in carrying out his responsibilities. As a result of this review, our board of directors has determined that Messrs. Tullman and Molineaux and Drs. Cha, Patel and Mehra, representing five of our six directors, are "independent directors" as defined under NASDAQ rules.

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the management of our business.

Audit Committee

Our audit committee reviews our internal accounting procedures and consults with and reviews the services provided by our independent registered public accountants. Our audit committee consists of three directors, _____, _____ and _____. Mr. _____ is the chairman of the audit committee and our board of directors has determined that Mr. _____ is an "audit committee financial expert" as defined by SEC rules and regulations. Our board of directors has determined that each of Messrs. _____, _____ and _____ are independent directors under NASDAQ listing

rules and under Rule 10A-3 under the Exchange Act, as amended. We intend to continue to evaluate the requirements applicable to us and we intend to comply with future requirements to the extent that they become applicable to our audit committee. The principal duties and responsibilities of our audit committee include:

- § appointing and retaining an independent registered public accounting firm to serve as independent auditor to audit our financial statements, overseeing the independent auditor's work and determining the independent auditor's compensation;
- § approving in advance all audit services and non-audit services to be provided to us by our independent auditor;
- § establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls, auditing or compliance matters, as well as for the confidential, anonymous submission by our employees of concerns regarding questionable accounting or auditing matters;
- § reviewing and discussing with management and our independent auditor the results of the annual audit and the independent auditor's review of our quarterly financial statements; and
- § conferring with management and our independent auditor about the scope, adequacy and effectiveness of our internal accounting controls, the objectivity of our financial reporting and our accounting policies and practices.

Compensation Committee

Our compensation committee reviews and determines the compensation of all our executive officers. Our compensation committee consists of directors, _____, and _____, each of whom is a non-employee member of our board of directors as defined in Rule 16b-3 under the Exchange Act. Mr. _____ is the chairman of the compensation committee. Our board of directors has determined that the composition of our compensation committee satisfies the applicable independence requirements under, and the functioning of our compensation committee complies with the applicable requirements of, stock exchange listing rules and SEC rules and regulations. We intend to continue to evaluate and intend to comply with all future requirements applicable to our compensation committee. The principal duties and responsibilities of our compensation committee include:

- § establishing and approving, and making recommendations to the board of directors regarding, performance goals and objectives relevant to the compensation of our chief executive officer, evaluating the performance of our chief executive officer in light of those goals and objectives and setting, or recommending to the full board of directors for approval, the chief executive officer's compensation, including incentive-based and equity-based compensation, based on that evaluation;
- § setting the compensation of our other executive officers, based in part on recommendations of the chief executive officer;
- § exercising administrative authority under our stock plans and employee benefit plans;
- § establishing policies and making recommendations to our board of directors regarding director compensation;
- § reviewing and discussing with management the compensation discussion and analysis that we may be required from time to time to include in SEC filings; and
- § preparing a compensation committee report on executive compensation as may be required from time to time to be included in our annual proxy statements or annual reports on Form 10-K filed with the SEC.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee consists of _____ directors, _____, _____ and _____. Mr. _____ is the chairman of the nominating and corporate governance committee. Our board of directors has determined that the composition of our nominating and corporate governance committee satisfies the applicable independence requirements under, and the functioning of our nominating and corporate governance committee complies with the applicable requirements of, stock exchange listing standards and SEC rules and regulations. We will continue to evaluate and will comply with all future requirements applicable to our nominating and corporate governance committee. The nominating and corporate governance committee's responsibilities include:

- § assessing the need for new directors and identifying individuals qualified to become directors;
- § recommending to the board of directors the persons to be nominated for election as directors and to each of the board's committees;
- § assessing individual director performance, participation and qualifications;
- § developing and recommending to the board corporate governance principles;
- § monitoring the effectiveness of the board and the quality of the relationship between management and the board; and
- § overseeing an annual evaluation of the board's performance.

Code of Business Conduct and Ethics for Employees, Executive Officers and Directors

Effective upon closing of this offering, we will adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Following the closing of this offering, the Code of Conduct will be available on our website at www.aclaristx.com. The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.

Compensation Committee Interlocks and Insider Participation

None of our directors who currently serve as members of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.

Non-Employee Director Compensation

With the exception of payments to NST Consulting, LLC for the services of Mr. Tullman, the chairman of our board of directors, we have not historically paid cash retainers or other cash compensation with respect to service on our board of directors, except for reimbursement of direct expenses incurred in connection with attending meetings of the board or committees. In January, August and December 2014, we awarded options to purchase 30,000 shares, 1,663 shares and 3,638 shares, respectively, of our common stock to Mr. Molineaux at exercise prices of \$0.12, \$0.21 and \$0.44 per share, respectively. In August and December 2014, we awarded options to purchase 66,528 shares and 150,000 shares of our common stock, respectively, to Mr. Tullman at exercise prices of \$0.21 and \$0.44 per share, respectively. Other than Messrs. Molineaux and Tullman, none of our non-employee directors held any options to purchase our common stock as of December 31, 2014.

The following table sets forth information regarding compensation earned for service on our board of directors during the year ended December 31, 2014 by our non-employee directors. Dr. Walker, our President and Chief Executive Officer, is also a director but does not receive any additional compensation

for his service as director. Dr. Walker's compensation as an executive officer is set forth below under "Executive Compensation — Summary Compensation Table."

Name	Fees Earned or Paid in Cash (\$)	Option Awards⁽¹⁾ (\$)	Non-equity Incentive Plan Compensation (\$)	Total (\$)
Stephen A. Tullman	100,000 ⁽²⁾	92,559 ⁽³⁾	30,000 ⁽⁴⁾	222,559
Albert Cha	—	—	—	—
Ketan Patel	—	—	—	—
Christopher Molineaux	—	5,407 ⁽⁵⁾	—	5,407
Anand Mehra	—	—	—	—

⁽¹⁾ The amounts reflect the full grant date fair value for options granted during 2014. The grant date fair value was computed in accordance with ASC Topic 718, *Compensation — Stock Compensation*. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the director will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note 8 to our audited financial statements included in this prospectus.

⁽²⁾ Represents the portion of Mr. Tullman's salary paid by NST Consulting, LLC that we reimburse pursuant to our services agreement with them. See "Certain Relationships and Related Party Transactions — Services Agreements with Ceptaris and NST."

⁽³⁾ As of December 31, 2014, Mr. Tullman held options to purchase 216,528 shares of our common stock. 25% of the total shares underlying these options vest one year from the grant date and the remaining shares vest in 36 equal monthly installments thereafter.

⁽⁴⁾ Mr. Tullman is eligible to receive a target bonus for up to 30% of the amounts we pay to NST Consulting, LLC for his services provided to us. Mr. Tullman's bonus is based upon our achievement of specified corporate goals, including our clinical development and capital raising activities. Based on our level of achievement for 2014, our compensation committee awarded Mr. Tullman 100% of his target bonus.

⁽⁵⁾ As of December 31, 2014, Mr. Molineaux held options to purchase 35,301 shares of common stock. 25% of the total shares underlying these options vest one year from the grant date and the remaining shares vest in 36 equal monthly installments thereafter.

We expect that our board of directors will adopt a director compensation policy for non-employee directors to be effective following the closing of this offering.

EXECUTIVE COMPENSATION

Our Chief Executive Officer and our two other most highly compensated executive officers for the year ended December 31, 2014 were:

- § Neal Walker, our President and Chief Executive Officer;
- § Christopher Powala, our Chief Operating Officer; and
- § Stuart Shanler, our Chief Scientific Officer.

We refer to these executive officers in this prospectus as our named executive officers.

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the year ended December 31, 2014. Under a services agreement, we provided the part-time services of Mr. Powala and Dr. Shanler to Alexar Therapeutics, Inc., a company under common control with us, and NST, LLC reimbursed us for these services based on the percentage of time the named executive officer spent on matters related to NST and Alexar Therapeutics, Inc. The salary amounts set forth in the table below represent the total salary earned by the named executive officer during the year ended December 31, 2014, including amounts reimbursed by NST, LLC to us.

Name and Principal Position	Year	Salary (\$)	Option Awards (\$)⁽¹⁾	Non-Equity Incentive Plan Compensation (\$)⁽²⁾	All Other Compensation (\$)⁽³⁾	Total (\$)
Neal Walker President and Chief Executive Officer	2014	339,900	241,420	101,970	10,400	693,690
Christopher Powala Chief Operating Officer	2014	300,760	79,875	90,228	10,400	481,263
Stuart Shanler Chief Scientific Officer	2014	283,250	77,602	84,975	44,000	489,827

- (1) The amounts reflect the full grant date fair value for awards granted during 2014. The grant date fair value was computed in accordance with ASC Topic 718, *Compensation — Stock Compensation*. Unlike the calculations contained in our financial statements, this calculation does not give effect to any estimate of forfeitures related to service-based vesting, but assumes that the executive will perform the requisite service for the award to vest in full. The assumptions we used in valuing options are described in Note 8 to our audited financial statements included in this prospectus.
- (2) The amounts reflect the bonus paid based on the achievement of specified corporate goals, as discussed further below under "— Narrative to Summary Compensation Table — Annual Bonus.
- (3) We reimbursed Dr. Shanler an amount of \$33,600 for corporate housing expenses that he incurred. The other amounts shown in the "All Other Compensation" column consist of company contributions made to the officer's 401(k) plan account.

Narrative to Summary Compensation Table

We review compensation annually for all employees, including our named executive officers. In setting executive base salaries and bonuses and granting equity incentive awards, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives.

The compensation committee of our board of directors has historically determined our executive officers' compensation. Our compensation committee typically reviews and discusses management's proposed compensation with the Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, the compensation committee then recommends the compensation for each executive officer. Our compensation committee, without members of management present, discusses and ultimately approves the compensation of our executive officers.

Annual Base Salary

In 2012, we entered into employment agreements or offer letters with each of our named executive officers that established initial base salaries and target bonus opportunities. The base salaries are reviewed periodically by our compensation committee. The following table presents the base salaries for each of our named executive officers for 2014 and 2015. The 2014 base salaries became effective on January 1, 2014 and the 2015 base salaries became effective on January 1, 2015 for all of the named executive officers.

<u>Name</u>	<u>2014 Base Salary (\$)</u>	<u>2015 Base Salary (\$)</u>
Neal Walker	339,900	344,999
Christopher Powala	300,760	305,221
Stuart Shanler	283,250	287,499

Annual Bonus

We seek to motivate and reward our executives for achievements relative to our corporate goals and expectations for each fiscal year. For 2014 and 2015, the target bonus was and is 30% of each named executive officer's base salary.

For 2014, target bonuses were based on our achievement of specified corporate goals, including our clinical development and capital raising activities. Based on the level of achievement, our compensation committee awarded each named executive officer 100% of his target bonus for the year. These actual bonus amounts are reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

Long-Term Incentives

Our 2012 equity compensation plan, or the 2012 plan, authorizes us to make grants to eligible recipients of non-qualified stock options, incentive stock options and other stock-based awards. All of our awards under this plan to date have been in the form of stock options.

We award stock options on the date the compensation committee approves the grant. We set the option exercise price and grant date fair value based on our per-share valuation on the date of grant. The shares underlying options granted under our 2012 typically vest 25% one year from the date of grant and the remaining shares vest in 36 equal monthly installments thereafter.

In August 2014, our compensation committee awarded options to Dr. Walker, Mr. Powala and Dr. Shanler to purchase 150,243 shares, 49,896 shares and 49,896 shares of our common stock, respectively. Each of these options has an exercise price of \$0.21 per share. In December 2014, our compensation committee approved additional option grants to Dr. Walker, Mr. Powala and Dr. Shanler to purchase 410,000 shares, 135,500 shares and 130,500 shares of our common stock, respectively. Each of these options has an exercise price of \$0.44 per share.

Other Compensation

Except for the benefits described above, we do not provide perquisites or personal benefits to our named executive officers. We do, however, pay the premiums for life, medical and dental insurance for all of our employees, including our named executive officers.

Employment Arrangements and Potential Payments upon Termination of Employment

In August 2012, we entered into an employment agreement with Dr. Walker under which he serves as our Chief Executive Officer and President. Under this agreement, Dr. Walker is eligible to receive severance benefits in specified circumstances.

In the event that we terminate Dr. Walker without cause, he resigns for good reason or his employment is terminated due to death or disability, Dr. Walker, or his estate, will be entitled to receive, upon execution and effectiveness of a release of claims, (i) an amount equal to 12 months of his then-current salary payable in accordance with our normal payroll practices, (ii) a lump sum payment of any approved but unpaid bonuses or portion thereof, (iii) any and all accrued employee benefits to which he is entitled and (iv) a direct payment by us to the applicable healthcare provider of 100% of the medical, vision, and dental coverage premiums due to maintain any COBRA coverage for which he is eligible and has appropriately elected for 12 months following termination; except that, in the event he is terminated following a change of control, he will be entitled to an additional lump sum payment equal to six months of base salary, less applicable deductions and withholdings, and up to six additional months of paid COBRA premiums.

In the event that Dr. Walker's employment is terminated upon nonrenewal of the employment contract by us, Dr. Walker will be entitled to receive, upon execution and effectiveness of a release of claims, (i) continued payment of his salary during a 120-day nonrenewal notice period, (ii) an amount equal to 12 months of his then-current salary payable in accordance with our normal payroll practices, (iii) any and all unpaid salary accrued and earned up to and including the effective date of termination, (iv) a lump sum of any approved but unpaid bonuses or portion thereof and (v) a direct payment by us to the applicable healthcare provider of 100% of the medical, vision, and dental coverage premiums due to maintain any COBRA coverage for which he is eligible and has appropriately elected, for eight months following termination. In the event that we terminate Dr. Walker with cause, he resigns without good reason, or his employment is terminated due to his nonrenewal of the employment contract by him, then he will not be entitled to receive severance benefits.

The following definitions are used in Dr. Walker's employment agreement:

- § "cause" means: (i) Dr. Walker's conviction of, or guilty plea to, a crime of moral turpitude, whether or not a felony, or a felony, other than traffic violations; (ii) any act or omission by him which constitutes gross negligence or a material breach of his duty of loyalty; (iii) if he is regularly under the influence of alcohol or illegal substances while performing services for us; (iv) any material breach by him of our personnel policies, including those prohibiting acts of discrimination, harassment or retaliation; or (v) a material violation or breach by him of his employment agreement, subject to specified exceptions;
- § "good reason" means, in the absence of events that would support a termination for cause: (i) there is a material failure by us to pay Dr. Walker's salary or additional compensation or benefits in accordance with the employment agreement; (ii) his annual base salary is materially decreased without his prior written consent; (iii) he is assigned duties substantially inconsistent with his title and the responsibilities set forth in his job description without his prior written consent; (iv) his place of employment is changed to a location that is greater than 50 miles from his current place of employment; or (v) any other material violation or breach by us of his employment agreement; provided, however, none of the above events will constitute good reason absent Dr. Walker providing us with proper notice and our failure to cure such event within 30 days of such notice; and
- § "change of control" means: (i) our consolidation or merger with or into any other corporation or other entity or person, or any other corporate reorganization, in which our stockholders immediately prior to

such consolidation, merger or reorganization, own, in the aggregate, less than 50% of the surviving entity's voting power or outstanding capital stock immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions to which we, or any of our stockholders is a party in which greater than 50% of our voting power or outstanding capital stock is transferred, or pursuant to which any person or group of affiliated persons obtains greater than 50% of our voting power or outstanding capital stock, excluding any consolidation or merger effected exclusively to change our domicile; or (ii) any sale, lease, or other disposition, including through a division or spin-off transaction, of all or substantially all of our assets or any of our subsidiaries' assets or any sale, lease or exclusive license or other disposition of all or substantially all of our intellectual property; provided, however that neither of the following constitutes a change of control: (A) transfers of capital stock by an existing stockholder as a result of death or otherwise for estate planning purposes or to such stockholder's affiliates or to any of our other existing stockholders; or (B) issuances of our equity securities in connection with financings for working capital and other general purposes.

In addition, we have entered into letter agreements with each of Mr. Powala and Dr. Shanler. Under the terms of the letter agreements, each of Mr. Powala and Dr. Shanler is entitled to receive severance benefits if there is a change of control of our company or we terminate his employment without cause.

The following definitions have been adopted in these letters agreements:

- § "cause" means: (i) the officer's conviction of, or guilty plea to, a crime of moral turpitude, whether or not a felony, or a felony, other than traffic violations; (ii) any act or omission by the officer which constitutes gross negligence or a material breach of his duty of loyalty; (iii) if the officer is regularly under the influence of alcohol or illegal substances while performing services for us; or (iv) any material breach by the officer of our personnel policies, including those prohibiting acts of discrimination, harassment or retaliation; and
- § "change of control" means: (i) our consolidation or merger with or into any other corporation or other entity or person, or any other corporate reorganization, in which our stockholders immediately prior to such consolidation, merger or reorganization, own, in the aggregate, less than 50% of the surviving entity's voting power or outstanding capital stock immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions to which we, or any of our stockholders is a party in which greater than 50% of our voting power or outstanding capital stock is transferred, or pursuant to which any person or group of affiliated persons obtains greater than 50% of our voting power or outstanding capital stock, excluding any consolidation or merger effected exclusively to change our domicile; or (ii) any sale, lease, or other disposition, including through a division or spin-off transaction, of all or substantially all of our assets or any of our subsidiaries' assets or any sale, lease or exclusive license or other disposition of all or substantially all of our intellectual property; provided, however that neither of the following constitutes a change of control: (A) transfers of capital stock by an existing stockholder as a result of death or otherwise for estate planning purposes or to such stockholder's affiliates or to any of our other existing stockholders; or (B) issuances of our equity securities in connection with financings for working capital and other general purposes.

In the event of a change of control, each of Mr. Powala and Dr. Shanler, upon execution and effectiveness of a release of claims, will be entitled to receive a bonus in an amount equal to 12 months of his regular monthly base salary as of the effective date of the change of control. In addition to these payments, if the officer is terminated without cause within 90 days after a change of control, then, upon execution and effectiveness of a release of claims, we will also pay directly to the applicable healthcare provider 100% of the medical, vision, and dental coverage premiums due to maintain any COBRA coverage for which the officer is eligible and has appropriately elected, for 12 months following termination.

We expect to enter into amended and restated employment agreements with each of our named executive officers prior to the closing of this offering.

In addition, each of our named executive officers hold restricted shares of common stock, which vest in equal monthly installments through July 13, 2016. These restricted shares are subject to full acceleration of vesting (a) upon the closing of this offering or a change of control, (b) upon the officer's death or disability or (c) if we terminate the officer without cause or the officer resigns for good reason.

Outstanding Equity Awards at End of 2014

The following table provides information about outstanding stock options and stock awards held by each of our named executive officers at December 31, 2014. All stock options were granted under our 2012 plan.

Name	Option Awards			Stock Awards		
	Number of Securities Underlying Unexercised Options (#)		Option Exercise Price (\$)	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested (\$) ⁽⁶⁾
	Exercisable	Unexercisable ⁽¹⁾				
Neal Walker	—	150,243 ⁽²⁾	0.21	08/12/2024	1,072,708 ⁽⁵⁾	568,535
	—	410,000 ⁽³⁾	0.44	12/07/2024		
Christopher Powala	—	49,896 ⁽²⁾	0.21	08/12/2024	356,250 ⁽⁴⁾	188,813
	—	135,500 ⁽³⁾	0.44	12/07/2024		
Stuart Shanler	—	49,896 ⁽²⁾	0.21	08/12/2024	356,250 ⁽⁵⁾	188,813
	—	130,500 ⁽³⁾	0.44	12/07/2024		

- (1) All options granted to date under our 2012 plan to the named executive officers are exercisable immediately, subject to a repurchase right in our favor that lapses as the option vests. This column reflects the number of options held by our named executive officers that were unvested, as opposed to unexercisable, as of December 31, 2014.
- (2) The unvested shares underlying this option vest as to 25% of the shares on August 13, 2015, with the remainder vesting in 36 equal monthly installments thereafter, subject to the officer's continued service through each applicable vesting date.
- (3) The unvested shares underlying this option vest as to 25% of the shares on December 8, 2015, with the remainder vesting in 36 equal monthly installments thereafter, subject to the officer's continued service through each applicable vesting date.
- (4) Consists of 178,125 restricted shares held by Mr. Powala directly and 178,125 restricted shares held by the Christopher V. Powala Aclaris Irrevocable Trust, of which Mr. Powala serves as the trustee. These restricted shares will vest in equal monthly installments through July 13, 2016. These restricted shares are subject to full acceleration of vesting (a) upon the closing of this offering or a change of control, (b) upon the officer's death or disability or (c) if we terminate the officer without cause or the officer resigns for good reason.
- (5) These restricted shares will vest in equal monthly installments through July 13, 2016. These restricted shares are subject to full acceleration of vesting (a) upon the closing of this offering or a change of control, (b) upon the officer's death or disability or (c) if we terminate the officer without cause or the officer resigns for good reason.
- (6) Based on the valuation of our common stock of \$0.53 per share as of December 8, 2014.

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during 2014.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or otherwise receive any benefits under, any nonqualified deferred compensation plan sponsored by us during 2014.

Equity Incentive Plans

2015 Equity Incentive Plan

We expect that our board of directors will adopt, and our stockholders will approve, prior to the closing of this offering our 2015 Equity Incentive Plan, or our 2015 plan. We do not expect to issue equity awards under our 2015 plan until after the closing of this offering. Our 2015 plan will provide for the grant of incentive stock options within the meaning of Section 422 of the Internal Revenue Code, or the Code, to our employees and our parent and subsidiary corporations' employees, and for the grant of nonstatutory stock options, restricted stock awards, restricted stock unit awards, stock appreciation rights, performance stock awards and other forms of stock compensation to our employees, including officers, consultants and directors. Our 2015 plan will also provide for the grant of performance cash awards to our employees, consultants and directors.

Authorized Shares

The maximum number of shares of our common stock that may be issued under our 2015 plan is _____ shares. The number of shares of our common stock reserved for issuance under our 2015 plan will automatically increase on January 1 of each year, beginning on January 1 of the year after the closing of this offering and ending on January 1, 2025, by _____ % of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by our board of directors. The maximum number of shares that may be issued pursuant to exercise of incentive stock options under the 2015 plan is _____.

Shares issued under our 2015 plan may be authorized but unissued or reacquired shares of our common stock. Shares subject to stock awards granted under our 2015 plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, will not reduce the number of shares available for issuance under our 2015 plan. Additionally, shares issued pursuant to stock awards under our 2015 plan that we repurchase or that are forfeited, as well as shares reacquired by us as consideration for the exercise or purchase price of a stock award or to satisfy tax withholding obligations related to a stock award, will become available for future grant under our 2015 plan.

Administration

Our board of directors, or a duly authorized committee thereof, has the authority to administer our 2015 plan. Our board of directors has delegated its authority to administer our 2015 plan to our compensation committee under the terms of the compensation committee's charter. Our board of directors may also delegate to one or more of our officers the authority to (i) designate employees other than officers to receive specified stock awards and (ii) determine the number of shares of our common stock to be subject to such stock awards. Subject to the terms of our 2015 plan, the administrator has the authority to determine the terms of awards, including recipients, the exercise price or strike price of stock awards, if any, the number of shares subject to each stock award, the fair market value of a share of our common stock, the vesting schedule applicable to the awards, together with any vesting acceleration, the form of consideration, if any, payable upon exercise or settlement of the stock award and the terms and conditions of the award agreements for use under our 2015 plan.

The administrator has the power to modify outstanding awards under our 2015 plan. Subject to the terms of our 2015 plan, the administrator has the authority to reprice any outstanding option or stock appreciation right, cancel and re-grant any outstanding option or stock appreciation right in exchange for new stock awards, cash or other consideration or take any other action that is treated as a repricing under GAAP with the consent of any adversely affected participant.

Section 162(m) Limits

No participant may be granted stock awards covering more than _____ shares of our common stock under our 2015 plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise price or strike price of at least 100% of the fair market value of our common stock on the date of grant. Additionally, no participant may be granted in a calendar year a performance stock award covering more than _____ shares of our common stock or a performance cash award having a maximum value in excess of \$ _____ million under our 2015 plan. These limitations enable us to grant awards that will be exempt from the \$1.0 million limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code.

Performance Awards

Our 2015 plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the \$1.0 million limitation on the income tax deductibility of compensation paid per covered executive officer imposed by Section 162(m) of the Code. To enable us to grant performance-based awards that will qualify, our compensation committee can structure such awards so that the stock or cash will be issued or paid pursuant to such award only following the achievement of specified pre-established performance goals during a designated performance period.

Corporate Transactions

Our 2015 plan provides that in the event of a specified corporate transaction, including without limitation a consolidation, merger or similar transaction involving our company, the sale, lease or other disposition of all or substantially all of the assets of our company or the consolidated assets of our company and our subsidiaries, or a sale or disposition of at least 50% of the outstanding capital stock of our company, the administrator will determine how to treat each outstanding equity award. The administrator may:

- § arrange for the assumption, continuation or substitution of a stock award by a successor corporation;
- § arrange for the assignment of any reacquisition or repurchase rights held by us to a successor corporation;
- § accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;
- § arrange for the lapse, in whole or in part, of any reacquisition or repurchase right held by us; or
- § cancel the stock award prior to the transaction in exchange for a cash payment, which may be reduced by the exercise price payable in connection with the stock award.

The administrator is not obligated to treat all equity awards or portions of equity awards, even those that are of the same type, in the same manner. The administrator may take different actions with respect to the vested and unvested portions of an equity award.

Change of Control

The administrator may provide, in an individual award agreement or in any other written agreement between us and the participant, that the equity award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. In the absence of such a provision, no such acceleration of the award will occur.

Plan Amendment or Termination

Our board has the authority to amend, suspend or terminate our 2015 plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. No incentive stock options may be granted after the tenth anniversary of the date our board of directors adopts our 2015 plan.

2012 Equity Compensation Plan

In August 2012, our board of directors adopted and our stockholders approved our 2012 equity compensation plan, or our 2012 plan. Our 2012 plan was most recently amended and restated by our board of directors and our stockholders in September 2014. Our 2012 plan provides for the grant of

incentive stock options within the meaning of Section 422 of the Code to our employees, and for the grant of nonqualified stock options and stock awards to our officers, directors, employees, consultants and advisers.

Authorized Shares

We have reserved an aggregate of 1,725,961 shares of our common stock for issuance under our 2012 plan. As of December 31, 2014, no shares of our common stock have been issued upon the exercise of options granted under our 2012 plan, options to purchase 1,725,961 shares of our common stock were outstanding at a weighted average exercise price of \$0.35 per share and no shares remained available for grant under our 2012 plan. Effective upon the closing of this offering, no further options or stock awards may be granted under our 2012 plan, but all outstanding stock awards will continue to be governed by their existing terms.

Administration

Our board of directors, or a committee thereof appointed by our board of directors, administers our 2012 plan and the option and stock awards granted under it. Our board of directors delegated its authority to administer our 2012 plan to our compensation committee.

Corporate Transactions

Our 2012 plan provides that the administrator may provide that, in the event of a specified change of control transaction, including without limitation a merger, consolidation or reorganization of our company with one or more other entities in which our company is not the surviving entity, a sale of substantially all of the assets of our company or any corporate reorganization which results in the disposition of at least 50% of the voting power of our company, one or more of the following actions may be taken:

- § provide that the options become exercisable, and that restrictions applicable to outstanding stock awards and restricted stock shall lapse;
- § the assumption or substitution of the options by a successor corporation;
- § the substitution of the stock awards and restricted stock by a successor corporation;
- § the purchase of outstanding options for an amount of cash or property that could have been received upon the exercise of the options had the options been fully vested; or
- § the termination of the options, provided that the holders of options are given a reasonable period of time to exercise the options, notwithstanding any limits on exercisability.

Amendment and Termination

Our board of directors may at any time amend our 2012 plan. However, our board of directors must obtain approval of our stockholders for any amendment requiring such approval under federal tax or federal securities laws, including an increase to the maximum number of shares of our common stock that may be issued under our 2012 plan. In addition, our board of directors may not materially impair the rights of a holder of any award previously granted under our 2012 plan without the consent of the holder of such award. Our 2012 plan will terminate in August 2022 or, if earlier, a date determined by our board of directors.

401(k) Plan

We maintain a tax-qualified retirement plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation subject to applicable annual Code limits. Currently, we match 100% of each eligible employee's contributions up to 4.0% of total eligible compensation. Employees' pre-tax contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. Employees are immediately and fully vested in their contributions, and our matching contribution is subject to a six-year vesting schedule. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan.

Limitations on Liability and Indemnification Matters

Upon the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- § any breach of the director's duty of loyalty to the corporation or its stockholders;
- § any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- § unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- § any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we are required to indemnify our directors to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board.

We have entered into indemnification agreements with each of our directors, and we expect to enter into indemnification agreements with each of our executive officers prior to the closing of this offering. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Rule 10b5-1 Sales Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since January 1, 2012 to which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our voting securities, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under "Executive Compensation."

Sales of Series A Redeemable Convertible Preferred Stock

In August 2012, we sold an aggregate of 20,890,000 shares of our Series A redeemable convertible preferred stock at a price of \$1.00 per share for an aggregate price of \$20.9 million, 19,445,000 shares of which were sold to holders of more than 5% of our voting securities, executive officers and members of our board of directors. Each share of Series A redeemable convertible preferred stock is convertible into one share of our common stock.

The table below summarizes these sales:

Purchaser	Shares of Series A Redeemable Convertible Preferred Stock Purchased	Aggregate Purchase Price
Entities affiliated with Vivo Ventures Fund VII, L.P. ⁽¹⁾	8,652,500	\$ 8,652,500
Beacon Bioventures Fund III Limited Partnership ⁽²⁾	8,652,500	8,652,500
Sofinnova Venture Partners VIII, L.P. ⁽³⁾	2,000,000	2,000,000
Kamil Ali-Jackson ⁽⁴⁾	10,000	10,000
Frank Ruffo	20,000	20,000
Stephen A. Tullman ⁽⁵⁾	110,000	110,000
Total	19,445,000	\$ 19,445,000

(1) Consists of 8,467,943 shares purchased by Vivo Ventures Fund VII, L.P. and 184,557 shares purchased by Vivo Ventures VII Affiliates Fund, L.P. Entities affiliated with Vivo Ventures Fund VII, L.P. are holders of more than 5% of our voting securities, and Albert Cha, M.D., Ph.D., a member of our board of directors, is a managing member of the general partner of these entities.

(2) Beacon Bioventures Fund III Limited Partnership is a holder of more than 5% of our voting securities, and Ketan Patel, M.D., a member of our board of directors, is affiliated with this entity.

(3) Sofinnova Venture Partners VIII, L.P. is a holder of more than 5% of our voting securities, and Anand Mehra, M.D., a member of our board of directors, is a managing member of the general partner of this entity.

(4) Consists of shares held jointly with Ms. Ali-Jackson's spouse.

(5) Consists of shares held by a trust of which Mr. Tullman's wife is the trustee.

Sales of Series B Redeemable Convertible Preferred Stock

In September 2014, we sold an aggregate of 6,451,057 shares of our Series B redeemable convertible preferred stock at a price of \$1.65 per share for an aggregate price of \$10.6 million, 6,101,222 shares of which were sold to holders of more than 5% of our voting securities, executive officers and members of our board of directors. Each share of Series B redeemable convertible preferred stock is convertible into one share of our common stock.

The table below summarizes these sales:

Purchaser	Shares of Series B Redeemable Convertible Preferred	Aggregate
	Stock Purchased	Purchase Price
Entities affiliated with Vivo Ventures Fund VII, L.P. ⁽¹⁾	1,818,182	\$ 3,000,000
Beacon Bioventures Fund III Limited Partnership	1,818,182	3,000,000
Sofinnova Venture Partners VIII, L.P.	2,424,242	4,000,000
Kamil Ali-Jackson ⁽²⁾	2,901	4,787
Frank Ruffo	5,802	9,573
Stephen A. Tullman ⁽³⁾	31,913	52,656
Total	6,101,222	\$ 10,067,016

(1) Consists of 1,779,400 shares purchased by Vivo Ventures Fund VII, L.P. and 38,782 shares purchased by Vivo Ventures VII Affiliates Fund, L.P.

(2) Consists of shares held jointly with Ms. Ali-Jackson's spouse.

(3) Consists of shares held by a trust of which Mr. Tullman's wife is the trustee.

Investors' Rights Agreement, Voting Agreement and Right of First Refusal and Co-Sale Agreement

In connection with the sales of redeemable convertible preferred stock described above, we entered into an investors' rights agreement, a voting agreement and a right of first refusal and co-sale agreement with the holders of preferred stock, including each of the persons and entities listed in the table above.

The investors' rights agreement, among other things:

- § grants our preferred stockholders specified registration rights with respect to shares of our common stock, including shares of common stock issued or issuable upon conversion of the shares of redeemable convertible preferred stock held by them;
- § obligates us to deliver periodic financial statements to some of the stockholders who are parties to the investors' rights agreement; and
- § grants a right of first refusal with respect to sales of our shares by us, subject to specified exclusions, which exclusions include the sale of the shares pursuant to this prospectus, to the stockholders who are parties to the investors' rights agreement.

For more information regarding the registration rights provided in this agreement, please refer to the section titled "Description of Capital Stock — Registration Rights." The provisions of this agreement other than those relating to registration rights will terminate upon the closing of this offering.

The voting agreement, among other things, provides for the voting of shares with respect to the constituency of our board of directors and the voting of shares in favor of specified transactions approved by our board of directors and the requisite majority of holders of our outstanding preferred stock. The voting agreement will terminate upon the closing of this offering.

The right of first refusal and co-sale agreement, among other things, grants our investors rights of first refusal and co-sale with respect to proposed transfers of our securities by specified stockholders and grants us rights of first refusal with respect to proposed transfers of our securities by specified stockholders. The right of first refusal and co-sale agreement will terminate upon the closing of this offering.

Services Agreements with Ceptaris and NST

In November 2012, we entered into a services agreement with Ceptaris Therapeutics, Inc., or the initial Ceptaris services agreement, under which Ceptaris Therapeutics, Inc., or Ceptaris, provided us with professional services, administrative support and office services. In September 2013, Ceptaris terminated the agreement in accordance with its terms, and we entered into a second services agreement with Ceptaris under which Ceptaris provided us with pharmaceutical development and management services. The second Ceptaris services agreement was amended in January 2014 pursuant to which we revised the scope of the services provided by Ceptaris to exclude personnel-related services and to eliminate our obligation to pay service fees related to those services. Ceptaris terminated the second Ceptaris services agreement in accordance with its terms in February 2014.

The chairman of our board of directors, Stephen A. Tullman, was the Chief Executive Officer of Ceptaris, and our Chief Legal Officer, Kamil Ali-Jackson, was the Chief Legal Officer of Ceptaris during the periods covered by the services agreements with Ceptaris. Our directors and executive officers in the aggregate owned _____ % of the ownership interests in Ceptaris.

Under the terms of the initial Ceptaris services agreement, we were obligated to pay Ceptaris a monthly service fee of \$16,487. Under the terms of the second Ceptaris services agreement, we were obligated to pay Ceptaris a monthly service fee of \$7,510. For the years ended December 31, 2012, 2013 and 2014, we paid Ceptaris an aggregate of \$64,716, \$166,211 and \$10,310, respectively, under the two services agreements.

In February 2014, we entered into a services agreement with NST, LLC, or the NST services agreement, pursuant to which NST, LLC provides us with pharmaceutical development, management and other administrative services, and we provide services to NST, LLC. Mr. Tullman is the manager of NST, LLC. In addition, several of our directors and executive officers are members of NST, LLC, including Mr. Tullman, Neal Walker, Frank Ruffo and Ms. Ali-Jackson. These directors and executive officers in the aggregate own 35.8% of the membership interests in NST, LLC.

The NST services agreement was amended in January 2015 pursuant to which NST, LLC assigned all interests, rights, duties and obligations under the NST services agreement to NST Consulting, LLC, a wholly owned subsidiary of NST, LLC. Mr. Tullman is also the manager of NST Consulting, LLC. We refer to NST, LLC and NST Consulting, LLC together in this prospectus as NST.

Under the terms of the NST services agreement, as amended, we are obligated to pay NST a monthly service fee of \$37,800, including benefits-related expenses. In addition, we have agreed to indemnify NST and its officers, employees and directors against all losses (i) arising out of, due to or in connection with the provision of services under the NST services agreement, subject to specified exceptions, and (ii) resulting from our or our affiliates' gross negligence or intentional misconduct. The NST services agreement may be terminated by either party upon 30 days' written notice.

In addition, through NST, we provide the part-time services of some of our executive officers to Alexar Therapeutics, Inc., a company under common control with us, and NST reimburses us for the services of these executive officers to Alexar Therapeutics, Inc. Specifically, NST reimburses us for 30% of the salaries of Messrs. Powala and Ruffo, 25% of Dr. Shanler's salary and 35% of Ms. Ali-Jackson's salary, plus 25% of each of these executive officers' benefits-related expenses. These personnel reimbursements from NST equal an aggregate payment of \$37,800 per month. Our directors and executive officers in the aggregate own 19.0% of Alexar Therapeutics, Inc.

NST provides us with the part-time services of some NST employees, including Mr. Tullman, and we reimburse NST for those services. We reimburse NST for 25% of Mr. Tullman's salary, plus 25% of his benefits-related expenses.

For the year ended December 31, 2014, the reimbursements to us from NST aggregated \$412,596 and the reimbursements from us to NST aggregated \$466,993.

Subleases

In September 2012, we entered into a sub-sublease agreement with Ceptaris for its leased office space in Malvern, Pennsylvania. Pursuant to this sub-sublease agreement, for the years ended December 31, 2012 and 2013, made aggregate payments of \$21,251 and \$51,669, respectively.

Upon the acquisition of Ceptaris in September 2013, we terminated the sub-sublease agreement with Ceptaris and entered into a sublease agreement with NeXeption, Inc. for the leased space. In March 2014, we entered into an Amended and Restated Sublease with NeXeption, Inc., which was subsequently amended in December 2014. Mr. Tullman is the President and Chief Executive Officer and owns 50.0% of the ownership interests of NeXeption, Inc. and Ms. Ali-Jackson is the Chief Legal Officer of NeXeption, Inc. For the years ended December 31, 2013 and 2014, we made aggregate payments pursuant to these sublease agreements with NeXeption, Inc. of \$16,435 and \$66,145, respectively.

Indemnification Agreements

Our amended and restated certificate of incorporation will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board.

In addition, we have entered into indemnification agreements with each of our directors, and we expect to enter into indemnification agreements with each of our executive officers prior to the closing of this offering. For more information regarding these agreements, see "Executive Compensation — Limitations on Liability and Indemnification Matters."

Directed Share Program

The underwriters have reserved for sale, at the initial public offering price, up to _____ shares of our common stock being offered for sale to our directors, officers and certain other persons associated with us as part of a directed share program. The directed share program will not limit the ability of our directors, officers and their family members, or holders of more than 5% of our capital stock, to purchase more than \$120,000 in value of our common stock. We do not currently know the extent to which these related persons will participate in our directed share program, if at all, or the extent to which they will purchase more than \$120,000 in value of our common stock.

Related Person Transaction Policy

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions that will become effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction will be a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director will not be covered by this policy. A related person will be any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct that we expect to adopt prior to the closing of this offering, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances including:

- § the risks, costs and benefits to us;
- § the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- § the availability of other sources for comparable services or products; and
- § the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy will require that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of January 31, 2015 for:

- § each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- § each of our named executive officers;
- § each of our directors; and
- § all of our current executive officers and directors as a group.

The percentage ownership information shown in the table is based upon 36,761,057 shares of common stock outstanding as of January 31, 2015, after giving effect to the conversion of all of our redeemable convertible preferred stock into 27,341,057 shares of common stock, which will occur upon the closing of this offering.

We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock issuable pursuant to the exercise of stock options that are either immediately exercisable or exercisable on or before April 1, 2015, which is 60 days after January 31, 2015. These shares are deemed to be outstanding and beneficially owned by the person holding those options for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws. The following table does not reflect any potential purchases by our stockholders, directors or executive officers pursuant to the directed share program or otherwise in this offering, which purchases, if any, will increase the percentage of shares owned after the offering of such stockholder from that set forth in the table below.

Except as otherwise noted below, the address for persons listed in the table is c/o Aclaris Therapeutics, Inc., 101 Lindenwood Drive, Suite 400, Malvern, PA 19355.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% or Greater Stockholders:			
Entities affiliated with Vivo Ventures Fund VII, L.P. ⁽¹⁾	11,470,682	31.2%	%
Beacon Bioventures Fund III Limited Partnership ⁽²⁾	10,470,682	28.5	
Sofinnova Venture Partners VIII, L.P. ⁽³⁾	4,424,242	12.0	
Named Executive Officers and Directors:			
Neal Walker ⁽⁴⁾	3,270,243	8.8	
Christopher Powala ⁽⁵⁾	1,085,396	2.9	
Stuart Shanler, M.D. ⁽⁶⁾	1,080,396	2.9	
Stephen A. Tullman ⁽⁷⁾	3,358,441	9.1	
Albert Cha, M.D., Ph.D. ⁽¹⁾	11,470,682	31.2	
Ketan Patel, M.D.	—	—	
Christopher Molineaux ⁽⁸⁾	35,301	*	
Anand Mehra, M.D. ⁽³⁾	4,424,242	12.0	
All current directors and executive officers as a group (10 persons) ⁽⁹⁾	25,428,212	66.8	

* Represents beneficial ownership of less than 1%.

- (1) Consists of (a) 10,267,363 shares of common stock issuable upon conversion of shares of preferred stock held by Vivo Ventures Fund VII, L.P., or Vivo VII, and (b) 1,000,000 shares of common stock and 223,339 shares of common stock issuable upon conversion of shares of preferred stock held by Vivo Ventures VII Affiliates Fund, L.P., or Vivo VII Affiliates. The shares directly held by Vivo VII and Vivo VII Affiliates are indirectly held by Vivo Ventures VII, LLC, or Vivo VII LLC, the sole general partner of each of Vivo VII and Vivo VII Affiliates. The managing members of Vivo VII LLC are Drs. Albert Cha (a member of our board of directors), Edgar Engleman and Frank Kung, each of whom may be deemed to have shared voting and dispositive power over the shares listed in the table. The principal business address of Vivo VII and Vivo VII Affiliates is 575 High Street, Suite 201, Palo Alto, California 94301.
- (2) Consists of 10,470,682 shares of common stock issuable upon conversion of shares of preferred stock held by Beacon Bioventures Fund III Limited Partnership, or Beacon III. The shares directly held by Beacon III are indirectly held by Beacon Bioventures Advisors Fund III Limited Partnership, or Beacon Advisors, its general partner, and Impresa Management LLC, the general partner of Beacon Advisors. Paul L. Mucci is the President of Impresa Management LLC and may be deemed to have voting and dispositive power with respect to the shares held by Beacon III. The principal business address of Beacon III is One Main Street, 13th Floor, Cambridge, Massachusetts 02142.
- (3) Consists of 4,424,242 shares of common stock issuable upon conversion of shares of preferred stock held by Sofinnova Venture Partners VIII, L.P., or Sofinnova VIII. Sofinnova Management VIII, L.L.C. is the general partner of Sofinnova VIII, and Anand Mehra, M.D. (a member of our board of directors), James Healy, M.D., Michael Powell, Ph.D. and Srinivas Akkaraju, M.D., Ph.D., the managing members of Sofinnova Management VIII, L.L.C., may be deemed to have shared voting and dispositive power with respect to such shares. The address of Sofinnova VIII is c/o Sofinnova Ventures, Inc., 3000 Sand Hill Road, Bldg. 4, Suite 250, Menlo Park, California 94025.
- (4) Consists of (a) 2,710,000 shares of common stock and (b) 560,243 shares of common stock underlying options that are exercisable within 60 days of January 31, 2015. Of the shares of common stock, 903,333 shares will be subject to a right of repurchase in our favor within 60 days of January 31, 2015 upon the occurrence of certain events. Does not include 1,800,000 shares of common stock held by NeXeption, LLC. Dr. Walker is a member of NeXeption, LLC, but does not have or share voting or dispositive power over the shares held by NeXeption, LLC.
- (5) Consists of (a) 450,000 shares of common stock held directly by Mr. Powala, (b) 450,000 shares of common stock held by the Christopher V. Powala Aclaris Irrevocable Trust, of which Mr. Powala serves as the trustee, and (c) 185,396 shares of common stock underlying options that are exercisable within 60 days of January 31, 2015. Of the shares of common stock, 150,000 shares held by Mr. Powala directly and 150,000 shares held by the trust will be subject to a right of repurchase in our favor within 60 days of January 31, 2015 upon the occurrence of certain events.
- (6) Consists of (a) 900,000 shares of common stock and (b) 180,396 shares of common stock underlying options that are exercisable within 60 days of January 31, 2015. Of the shares of common stock, 300,000 shares will be subject to a right of repurchase in our favor within 60 days of January 31, 2015 upon the occurrence of certain events.
- (7) Consists of (a) 1,200,000 shares of common stock held by the 2007 Irrevocable Trust of Stephen A. Tullman, of which Mr. Tullman's wife serves as the trustee, (b) 31,913 shares of common stock issuable upon conversion of shares of preferred stock held by the 2007 Irrevocable Trust of Stephen A. Tullman, (c) 1,800,000 shares of common stock held by NeXeption, LLC, of which Mr. Tullman is the Manager and, accordingly, may be deemed to share voting and dispositive power, and (d) 216,528 shares of common stock underlying options that are exercisable within 60 days of January 31, 2015. Of the shares of common stock held by Mr. Tullman directly, 400,000 shares will be subject to a right of repurchase in our favor within 60 days of January 31, 2015 upon the occurrence of certain events.
- (8) Consists of shares of common stock underlying options that are exercisable within 60 days of January 31, 2015.
- (9) Consists of (a) 9,030,000 shares of common stock, (b) 15,075,540 shares of common stock issuable upon conversion of shares of preferred stock and (d) 1,322,672 shares of common stock underlying options that are exercisable, subject to a right of repurchase in our favor, within 60 days of January 31, 2015. Of the shares of common stock, 2,076,667 shares will be subject to a right of repurchase in our favor within 60 days of January 31, 2015 upon the occurrence of certain events.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.

General

Upon the closing of this offering, our amended and restated certificate of incorporation will authorize us to issue up to _____ shares of common stock, \$0.00001 par value per share, and _____ shares of preferred stock, \$0.00001 par value per share, all of which shares of preferred stock will be undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time. As of January 31, 2015, we had outstanding 9,420,000 shares of common stock, held by 14 stockholders of record. As of January 31, 2015, after giving effect to the conversion of all outstanding preferred stock into 27,341,057 shares of common stock, there would have been 36,761,057 shares of common stock issued and outstanding, held of record by approximately 40 stockholders.

Common Stock

Voting Rights

Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Under our amended and restated certificate of incorporation and amended and restated bylaws, our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

As of January 31, 2015, there were outstanding 27,341,057 shares of redeemable convertible preferred stock, consisting of 20,890,000 shares of Series A redeemable convertible preferred stock and 6,451,057 shares of Series B redeemable convertible preferred stock. All currently outstanding shares of redeemable convertible preferred stock will be converted into an aggregate of 27,341,057 shares of common stock upon the closing of this offering.

Following the closing of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to _____ shares of preferred stock in one or more series, to establish from

time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change of control of our company and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock.

We have no present plans to issue any shares of preferred stock following the closing of this offering.

Options

As of January 31, 2015, under our 2012 plan, options to purchase an aggregate of 1,725,961 shares of common stock were outstanding. For additional information regarding the terms of this plan, see "Executive Compensation — Equity Incentive Plans."

Registration Rights

We and the holders of our existing redeemable convertible preferred stock have entered into an amended and restated investors' rights agreement. The registration rights provisions of this agreement provide those holders with demand, piggyback and Form S-3 registration rights with respect to the shares of common stock currently held by them and issuable to them upon conversion of our redeemable convertible preferred stock in connection with our initial public offering.

Demand Registration Rights

At any time beginning six months following the effective date of the registration statement of which this prospectus is a part, the holders of at least 5% of the outstanding shares issuable upon conversion of our redeemable convertible preferred stock in the aggregate have the right to demand that we file up to a total of two registration statements, as long as the anticipated aggregate offering price, net of underwriting discounts and commissions, would exceed \$5.0 million. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to effect the registration as soon as practicable, but in any event no later than 90 days after the receipt of such request. An aggregate of _____ shares of common stock will be entitled to these demand registration rights.

Piggyback Registration Rights

At any time after the closing of this offering, if we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, the holders of shares of common stock that are issued upon conversion of our redeemable convertible preferred stock and the holders of shares of our common stock will each be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances. An aggregate of _____ shares of common stock will be entitled to these piggyback registration rights.

Registration on Form S-3

At any time after we become eligible to file a registration statement on Form S-3, the holders of shares of common stock that are issued upon conversion of our redeemable convertible preferred stock and the holders of shares of our common stock will each be entitled, upon any such holder's written request, to have such shares registered by us on a Form S-3 registration statement at our expense. These Form S-3 registration rights are subject to other specified conditions and limitations, including the condition that the anticipated aggregate offering price, net of underwriting discounts and commissions, exceeds \$5.0 million. Upon receipt of this request, the holders of shares of common stock that are issued upon conversion of our redeemable convertible preferred stock and the holders of shares of our common stock will each be entitled to participate in this registration. An aggregate of _____ shares of common stock will be entitled to these Form S-3 registration rights.

Expenses of Registration

We will pay all expenses relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, subject to specified conditions and limitations.

Termination of Registration Rights

The registration rights granted under the investors' rights agreement will terminate upon the earlier of the fifth anniversary of the closing of this offering, a liquidation event or at such time as all shares held by the preferred stockholders are eligible to be sold without restriction pursuant to Rule 144 under the Securities Act of 1933, as amended, within any 90-day period.

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- § before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- § upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- § on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66²/₃% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- § any merger or consolidation involving the corporation and the interested stockholder;
- § any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- § subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- § any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or

- § the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Certificate of Incorporation and Bylaws to be in Effect Upon the Closing of this Offering

Our amended and restated certificate of incorporation to be in effect upon the closing of this offering, or our restated certificate, will provide for our board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our restated certificate and our amended and restated bylaws to be effective upon the closing of this offering, or our restated bylaws, will also provide that directors may be removed by the stockholders only for cause upon the vote of 66²/3% or more of our outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Our restated certificate and restated bylaws will also provide that all stockholder actions must be effected at a duly called meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. Our restated bylaws will also provide that only our chairman of the board, chief executive officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

Our restated bylaws will also provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing, and will specify requirements as to the form and content of a stockholder's notice.

Our restated certificate and restated bylaws will provide that the stockholders cannot amend many of the provisions described above except by a vote of 66²/3% or more of our outstanding common stock.

The combination of these provisions will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Choice of Forum

Our restated certificate will provide that the Court of Chancery of the State of Delaware will be the exclusive forum for:

- § any derivative action or proceeding brought on our behalf;
- § any action asserting a breach of fiduciary duty;
- § any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our restated certificate, or our amended and restated bylaws; or
- § any action asserting a claim against us that is governed by the internal affairs doctrine.

The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with any action, a court could find the choice of forum provisions contained in our restated certificate to be inapplicable or unenforceable in such action.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is . The transfer agent's address is .

NASDAQ Global Market Listing

We intend to apply for listing of our common stock on The NASDAQ Global Market under the trading symbol "ACRS."

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, no public market existed for our common stock. Future sales of shares of our common stock in the public market after this offering, or the perception that these sales could occur, could adversely affect prevailing market prices for our common stock and could impair our future ability to raise equity capital.

Based on the number of shares outstanding as of _____, upon the closing of this offering and assuming no exercise of the underwriters' option to purchase additional shares, _____ shares of common stock will be outstanding, assuming no outstanding options are exercised. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our "affiliates," as that term is defined under Rule 144 under the Securities Act. The remaining _____ shares of common stock held by existing stockholders are "restricted securities," as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 promulgated under the Securities Act.

As a result of contractual restrictions described below and the provisions of Rules 144 and 701, the shares sold in this offering and the restricted securities will be available for sale in the public market as follows:

- § the _____ shares sold in this offering and _____ of the existing restricted shares will be eligible for immediate sale upon the closing of this offering;
- § approximately _____ restricted shares will be eligible for sale in the public market 90 days after the date of this prospectus, subject to the volume, manner of sale and other limitations under Rule 144 and Rule 701; and
- § approximately _____ restricted shares will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701.

Rule 144

In general, persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of the company who owns either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

Non-Affiliates

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- § the restricted securities have been held for at least six months, including the holding period of any prior owner other than one of our affiliates;
- § we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- § we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of restricted securities without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting.

Affiliates

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- § 1% of the number of shares of our common stock then outstanding, which will equal approximately _____ shares immediately after the closing of this offering based on the number of shares outstanding as of _____; or
- § the average weekly trading volume of our common stock on The NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section of this prospectus titled "Underwriting" and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

Form S-8 Registration Statements

As soon as practicable after the closing of this offering, we intend to file with the SEC one or more registration statements on Form S-8 under the Securities Act to register the shares of our common stock that are issuable pursuant to our 2012 plan and 2015 plan. These registration statements will become effective immediately upon filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements described below and Rule 144 limitations applicable to affiliates.

Lock-Up Agreements

We and the holders of substantially all of our common stock outstanding on the date of this prospectus, including each of our executive officers and directors, have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our shares of common stock, any options to purchase shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock, without the prior written consent of the representatives of the underwriters for a period of 180 days from the date of this prospectus.

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS

The following is a general discussion of the material U.S. federal income and estate tax considerations applicable to non-U.S. holders with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. All prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock. In general, a non-U.S. holder means a beneficial owner of our common stock (other than a partnership or an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not, for U.S. federal income tax purposes:

- § an individual who is a citizen or resident of the United States;
- § a corporation, or an entity treated as a corporation for U.S. federal income tax purposes, created or organized in the United States or under the laws of the United States or of any state thereof or the District of Columbia;
- § an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- § a trust if (1) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons have the authority to control all of the trust's substantial decisions or (2) the trust has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing U.S. Treasury Regulations promulgated thereunder, published administrative rulings and judicial decisions, all as in effect as of the date of this prospectus. These laws are subject to change and to differing interpretation, possibly with retroactive effect. Any change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus.

We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any aspects of U.S. state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as holders that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below), corporations that accumulate earnings to avoid U.S. federal income tax, tax-exempt organizations, banks, financial institutions, insurance companies, real estate investment trusts, brokers, dealers or traders in securities, commodities or currencies, tax-qualified retirement plans, holders subject to the alternative minimum tax or the Medicare contribution tax, holders who hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation, holders holding our common stock as part of a hedge, straddle or other risk reduction strategy, conversion transaction or other integrated investment, holders deemed to sell our common stock under the constructive sale provisions of the Code, controlled foreign corporations, passive foreign investment companies and certain former U.S. citizens or long-term residents.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as partnerships for U.S. federal income tax purposes) or persons that hold their common stock through such partnerships. If a partnership, including any entity or arrangement treated as a partnership for U.S. federal income tax purposes, holds shares of our common stock, the U.S. federal income tax treatment of a partner in such partnership will generally depend upon the status of the partner and the activities of the partnership. Such partners and partnerships should consult their tax advisors regarding the tax consequences of the purchase, ownership and disposition of our common stock.

There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein, and we have not obtained, nor do we intend to obtain, a ruling with respect to the U.S. federal income or estate tax consequences to a non-U.S. holder of the purchase, ownership or disposition of our common stock.

Distributions on Our Common Stock

Distributions, if any, on our common stock generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such holder's adjusted tax basis in the common stock. Any remaining excess will be treated as capital gain from the sale or exchange of such common stock, subject to the tax treatment described below in "Gain on Sale, Exchange or Other Disposition of Our Common Stock." Any such distribution will also be subject to the discussion below under the heading "Foreign Accounts."

Dividends paid to a non-U.S. holder will generally be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

Gain on Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, in general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other disposition of shares of our common stock unless:

- § the gain is effectively connected with a U.S. trade or business of the non-U.S. holder and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed base maintained in the United States by such non-U.S. holder, in which case the non-U.S. holder generally will be taxed at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "Distributions on Our Common Stock" also may apply;

- § the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States) provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- § our common stock constitutes a U.S. real property interest because we are, or have been, at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation." Even if we are or become a U.S. real property holding corporation, provided that our common stock is regularly traded on an established securities market, our common stock will be treated as a U.S. real property interest only with respect to a non-U.S. holder that holds more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. In such case, such non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to U.S. persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will continue to be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the dividends on our common stock paid to such holder and the tax withheld, if any, with respect to such dividends. Non-U.S. holders will have to comply with specific certification procedures to establish that the holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder may be allowed as a credit against the non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that the required information is timely furnished to the IRS.

Foreign Accounts

The Foreign Account Tax Compliance Act provisions of the Hiring Incentives to Restore Employment Act, or FATCA, generally imposes a U.S. federal withholding tax of 30% on dividends and the gross proceeds of a disposition of our common stock paid to a "foreign financial institution" (as specifically defined for this purpose), unless such institution enters into an agreement with the U.S. government to, among other things, withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). A U.S. federal withholding tax of 30% also applies to dividends and the gross proceeds of a disposition of our common stock paid to a non-financial foreign entity (as specifically defined for this purpose), unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding substantial direct and indirect U.S. owners of the entity. The withholding provisions described above currently apply to dividends paid on our common stock and will generally apply with respect to gross proceeds of a sale or other disposition of our common stock on or after January 1, 2017. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE AND LOCAL AND NON-U.S. TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGES IN APPLICABLE LAWS.

U.S. Federal Estate Tax

Shares of our common stock that are owned or treated as owned at the time of death by an individual who is not a citizen or resident of the United States, as specifically defined for U.S. federal estate tax purposes, are considered U.S. situs assets and will be included in the individual's gross estate for U.S. federal estate tax purposes. Such shares, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated _____, 2015, among us and Jefferies LLC and Citigroup Global Markets Inc., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

<u>Underwriter</u>	<u>Number of Shares</u>
Jefferies LLC	
Citigroup Global Markets Inc.	
William Blair & Company, L.L.C.	
Total	

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the pricing of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$ _____ per share of common stock. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of \$ _____ per share of common stock to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such

amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	Per Share		Total	
	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares	Without Option to Purchase Additional Shares	With Option to Purchase Additional Shares
Public offering price	\$	\$	\$	\$
Underwriting discounts and commissions paid by us	\$	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$	\$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$. We have also agreed to reimburse the underwriters for certain expenses, including an amount not to exceed \$ in connection with the clearance of this offering with the Financial Industry Regulatory Authority, as set forth in the underwriting agreement.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

We intend to apply to have our common stock approved for listing on The NASDAQ Global Market under the trading symbol "ACRS."

Stamp Taxes

If you purchase shares of common stock offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock have agreed, subject to specified exceptions, not to directly or indirectly:

- § sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended, or
- § otherwise dispose of any shares of common stock or options to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or
- § publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Citigroup Global Markets Inc.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Jefferies LLC and Citigroup Global Markets Inc. may, in their discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter's purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock

originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we, nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the websites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' websites and any information contained in any other website maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Directed Share Program

At our request, the underwriters have reserved for sale at the initial public offering price up to _____ shares of common stock for employees, directors and other persons associated with us who have expressed an interest in purchasing shares in the offering. The number of shares of common stock available for sale to the general public in the offering will be reduced to the extent these persons purchase the directed shares in the program. Any directed shares not so purchased will be offered by the underwriters to the general public on the same terms as the other shares. Except for certain participants who have entered into lock-up agreements as contemplated above, each person buying shares through the directed share program has agreed that, for a period of 180 days from and including the date of this prospectus, he or she will not, without the prior written consent of _____, dispose of or hedge any shares of common stock or any securities convertible into or exchangeable for shares of common stock with respect to shares purchased in the program. For those participants who have entered into lock-up agreements as contemplated above, the lock-up agreements contemplated therein shall govern with respect to their purchases of shares of common stock in the program. _____ in its sole discretion may release any of the securities subject to these lock-up agreements at any time. We have agreed to indemnify the underwriters against certain liabilities and expenses, including liabilities under the Securities Act, in connection with sales of the directed shares.

Other Activities and Relationships

The underwriter and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in

our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Selling Restrictions

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- § a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- § a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- § a person associated with the Company under Section 708(12) of the Corporations Act; or
- § a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

European Economic Area

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), an offer to the public of any common shares which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- § to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;
- § to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- § in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer common shares to the public" in relation to the common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common shares to be offered so as to enable an investor to decide to purchase or subscribe to the common shares, as the same may be varied in that

Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

Hong Kong

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong ("SFO") and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong ("CO") or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the common stock is subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- § a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- § a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common stock pursuant to an offer made under Section 275 of the SFA except:
- § to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- § where no consideration is or will be given for the transfer;
- § where the transfer is by operation of law;
- § as specified in Section 276(7) of the SFA; or
- § as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange ("SIX") or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, the Company or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes ("CISA"). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

United Kingdom

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "relevant person").

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, Reston, Virginia. Certain legal matters related to this offering will be passed upon for the underwriters by Latham & Watkins LLP.

EXPERTS

The financial statements as of December 31, 2013 and 2014 and for each of the two years in the period ended December 31, 2014 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and website of the SEC referred to above. We also maintain a website at www.aclaristx.com, at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Aclaris Therapeutics, Inc.

In our opinion, the accompanying balance sheets and the related statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' deficit and of cash flows, present fairly, in all material respects, the financial position of Aclaris Therapeutics, Inc. at December 31, 2013 and 2014, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2014 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania
April 2, 2015

ACLARIS THERAPEUTICS, INC.
BALANCE SHEETS

(In thousands, except share and per share data)

	December 31,		Pro Forma
	2013	2014	December 31, 2014 (unaudited)
Assets			
Current assets:			
Cash and cash equivalents	\$ 9,588	\$ 10,757	\$ 10,757
Marketable securities	3,736	5,373	5,373
Prepaid expenses and other current assets	62	204	204
Total current assets	13,386	16,334	16,334
Marketable securities	802	518	518
Property and equipment, net	19	515	515
Other assets	—	10	10
Total assets	<u>\$ 14,207</u>	<u>\$ 17,377</u>	<u>\$ 17,377</u>
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)			
Current liabilities:			
Accounts payable	\$ 353	\$ 1,263	\$ 1,263
Accrued expenses	14	188	188
Total current liabilities	367	1,451	1,451
Deferred rent	3	4	4
Total liabilities	370	1,455	1,455
Commitments and contingencies (Note 10)			
Redeemable convertible preferred stock (Series A and B), \$0.00001 par value; 20,890,000 and 34,090,000 shares authorized at December 31, 2013 and 2014, respectively; 20,890,000 and 27,341,057 shares issued and outstanding at December 31, 2013 and 2014, respectively; aggregate liquidation preference of \$35,882 at December 31, 2014; no shares issued or outstanding, pro forma at December 31, 2014	23,000	36,677	—
Stockholders' equity (deficit):			
Common stock, \$0.00001 par value; 41,000,000 and 77,000,000 shares authorized at December 31, 2013 and 2014, respectively; 9,420,000 shares issued and outstanding at December 31, 2013 and 2014; 36,761,057 shares issued and outstanding, pro forma at December 31, 2014	—	—	—
Additional paid-in capital	—	—	36,677
Accumulated other comprehensive income (loss)	3	(6)	(6)
Accumulated deficit	(9,166)	(20,749)	(20,749)
Total stockholders' equity (deficit)	(9,163)	(20,755)	15,922
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 14,207</u>	<u>\$ 17,377</u>	<u>\$ 17,377</u>

The accompanying notes are an integral part of these financial statements.

ACLARIS THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Year Ended December 31,	
	2013	2014
Revenue	\$ —	\$ —
Operating expenses:		
Research and development	3,488	6,507
General and administrative	1,769	2,026
Total operating expenses	5,257	8,533
Loss from operations	(5,257)	(8,533)
Interest income	21	16
Net loss	(5,236)	(8,517)
Accretion of redeemable convertible preferred stock to redemption value	(1,740)	(2,054)
Net loss attributable to common stockholders	\$ (6,976)	\$ (10,571)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.87)	\$ (1.78)
Weighted average common shares outstanding, basic and diluted	3,730,654	5,934,302
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		\$ (0.30)
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)		28,467,995
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities, net of tax of \$0	3	(9)
Total other comprehensive income (loss)	3	(9)
Comprehensive loss	\$ (5,233)	\$ (8,526)

The accompanying notes are an integral part of these financial statements.

**ACLARIS THERAPEUTICS, INC.
STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK
AND STOCKHOLDERS' DEFICIT**

(In thousands, except share data)

	Series A and B Redeemable Convertible Preferred Stock		Common Stock			Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Par Value	Additional Paid-in Capital			
Balance at December 31, 2012	20,890,000	\$ 21,260	9,420,000	\$ —	\$ —	\$ —	\$ (2,190)	\$ (2,190)
Unrealized gain on marketable securities	—	—	—	—	—	3	—	3
Accretion of redeemable convertible preferred stock to redemption value	—	1,740	—	—	—	—	(1,740)	(1,740)
Net loss	—	—	—	—	—	—	(5,236)	(5,236)
Balance at December 31, 2013	20,890,000	23,000	9,420,000	—	—	3	(9,166)	(9,163)
Issuance of Series B redeemable convertible preferred stock and purchased put option, net of issuance costs of \$60	6,451,057	11,623	—	—	—	—	(1,039)	(1,039)
Unrealized loss on marketable securities	—	—	—	—	—	(9)	—	(9)
Stock-based compensation expense	—	—	—	—	27	—	—	27
Accretion of redeemable convertible preferred stock to redemption value	—	2,054	—	—	(27)	—	(2,027)	(2,054)
Net loss	—	—	—	—	—	—	(8,517)	(8,517)
Balance at December 31, 2014	<u>27,341,057</u>	<u>\$ 36,677</u>	<u>9,420,000</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ (6)</u>	<u>\$ (20,749)</u>	<u>\$ (20,755)</u>

The accompanying notes are an integral part of these financial statements.

**ACLARIS THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS**

(In thousands)

	Year Ended December 31,	
	2013	2014
Cash flows from operating activities:		
Net loss	\$ (5,236)	\$ (8,517)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	11	12
Stock-based compensation expense	—	27
Deferred rent	3	1
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	7	(152)
Accounts payable	303	819
Accrued expenses	(8)	174
Net cash used in operating activities	<u>(4,920)</u>	<u>(7,636)</u>
Cash flows from investing activities:		
Purchases of property and equipment	—	(417)
Purchases of marketable securities	(4,535)	(5,035)
Proceeds from sales and maturities of marketable securities	—	3,673
Net cash used in investing activities	<u>(4,535)</u>	<u>(1,779)</u>
Cash flows from financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	10,584
Net cash provided by financing activities	—	10,584
Net increase (decrease) in cash and cash equivalents	(9,455)	1,169
Cash and cash equivalents at beginning of year	19,043	9,588
Cash and cash equivalents at end of year	<u>\$ 9,588</u>	<u>\$ 10,757</u>
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment purchases included in accounts payable	\$ —	\$ 91
Accretion of redeemable convertible preferred stock to redemption value	\$ 1,740	\$ 2,054
Fair value of preferred stock purchased put option on date of issuance	\$ —	\$ 1,039

The accompanying notes are an integral part of these financial statements.

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share data)

1. Nature of Business and Basis of Presentation

Aclaris Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in 2012. The Company is a clinical-stage specialty pharmaceutical company focused on identifying, developing and commercializing innovative and differentiated topical drugs to address significant unmet needs in dermatology. The Company's lead drug candidate, A-101, is a proprietary high-concentration hydrogen peroxide topical solution that the Company is developing as a prescription treatment for seborrheic keratosis ("SK"), a common non-malignant skin tumor. The Company has completed three clinical trials of A-101 in patients with SK.

The Company has not generated any revenue and has incurred losses since inception. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of drug candidate development; technological uncertainty; uncertainty regarding patents and proprietary rights; having no commercial manufacturing experience, marketing or sales capability or experience; and dependence on key personnel, compliance with government regulations and the need to obtain additional financing. Drug candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

The Company's drug candidates are in the development stage. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The Company's financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced negative cash flows and had an accumulated deficit of \$20,749 as of December 31, 2014. As of December 31, 2014, the Company had cash and cash equivalents of \$10,757 and marketable securities of \$5,891. The Company expects that its cash, cash equivalents and marketable securities at December 31, 2014 should be sufficient to fund its operating expenses and capital expenditure requirements through at least December 31, 2015. The future viability of the Company is dependent on its ability to generate cash from operating activities or to raise additional capital to finance its operations. The Company's failure to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies.

The Company is seeking to complete an initial public offering of its common stock, which would provide additional capital to fund its operations. Upon the closing of a qualified public offering on specified terms, all of the Company's outstanding redeemable convertible preferred stock will convert into shares of common stock. In the event the Company does not complete an initial public offering, the Company expects to seek additional funding through private financings, debt financing, collaboration agreements or government grants. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaboration arrangements or obtain government grants. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders. If the Company is

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

1. Nature of Business and Basis of Presentation (Continued)

unable to obtain funding, the Company could be forced to delay, reduce or eliminate its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP").

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of common stock, stock-based awards and a purchased put option.

Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

Unaudited Pro Forma Information

The accompanying unaudited pro forma balance sheet as of December 31, 2014 has been prepared to give effect to the conversion of all outstanding shares of redeemable convertible preferred stock into 27,341,057 shares of common stock as if the proposed initial public offering had occurred on December 31, 2014.

In the accompanying statements of operations, unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2014 have been prepared to give effect to the conversion of all outstanding shares of redeemable convertible preferred stock into shares of common stock as if the proposed initial public offering had occurred on the later of January 1, 2014 or the issuance date of the redeemable convertible preferred stock.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include salaries, stock-based compensation and benefits of employees, fees paid under a third-party assignment agreement and other operational costs related to the Company's research and development activities, including allocated facility-related expenses and external costs of outside vendors engaged to conduct both pre-clinical studies and clinical trials.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of its studies and clinical trials, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates are made in determining the accrued balances at the end of any

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees and directors based on the fair value on the date of grant and recognizes compensation expense of those awards, net of estimated forfeitures, over the requisite service period, which is generally the vesting period of the respective award. Generally, the Company issues stock options and restricted stock awards with only service-based vesting conditions and records the expense for these awards using the straight-line method.

The Company measures stock-based awards granted to consultants and non-employees based on the fair value of the award on the date on which the related service is complete. Compensation expense is recognized over the period during which services are rendered by such consultants and non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of these awards is remeasured using the then-current fair value of the Company's common stock and updated assumption inputs in the Black-Scholes option-pricing model.

The Company classifies stock-based compensation expense in its statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company recognizes compensation expense for only the portion of awards that are expected to vest. In developing a forfeiture rate estimate, the Company has considered its historical experience to estimate pre-vesting forfeitures for service-based awards. The impact of a forfeiture rate adjustment will be recognized in full in the period of adjustment, and if the actual forfeiture rate is materially different from the Company's estimate, the Company may be required to record adjustments to stock-based compensation expense in future periods.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The fair value of each restricted stock award is measured as the aggregate difference between the purchase price per share of the award, if any, and the fair value per share of the Company's common stock on the date of grant.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Accretion of Redeemable Convertible Preferred Stock

Accretion of redeemable convertible preferred stock includes the accretion of accruing dividends on and issuance costs of the Company's Series A and Series B redeemable convertible preferred stock. The carrying values of the Series A and Series B redeemable convertible preferred stock are being accreted to their respective redemption values, using the effective interest method, from the date of issuance to the earliest date the holders can demand redemption.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. Comprehensive loss is comprised of net loss and unrealized gains (losses) on marketable securities.

Net Loss per Share

Basic net loss per share is computed using the weighted average number of common shares outstanding during the period. Diluted net loss per share is computed using the sum of the weighted average number of common shares outstanding during the period and, if dilutive, the weighted average number of potential shares of common stock, including the assumed exercise of stock options and unvested restricted stock. The Company applies the two-class method to calculate its basic and diluted net loss per share attributable to common stockholders, as its redeemable convertible preferred stock and common stock are participating securities. The two-class method is an earnings allocation formula that treats a participating security as having rights to earnings that otherwise would have been available to common stockholders. However, the two-class method does not impact the net loss per share of common stock as the Company was in a net loss position for each of the periods presented and preferred stockholders do not participate in losses.

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

The Company's redeemable convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Similarly, restricted stock awards granted by the Company entitle the holder of such awards to dividends declared or paid by the board of directors, regardless of whether such awards are unvested, as if such shares were outstanding common shares at the time of the dividend. However, the unvested restricted stock awards are not entitled to share in the residual net assets (deficit) of the Company. Accordingly, in periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts, are stated at fair value.

Marketable Securities

Marketable securities with original maturities of greater than three months and remaining maturities of less than one year from the balance sheet date are classified as short term. Marketable securities with remaining maturities of greater than one year from the balance sheet date are classified as long term.

The Company classifies all of its marketable securities as available-for-sale securities. The Company's marketable securities are measured and reported at fair value using quoted prices in markets that are not active for identical or similar securities. Unrealized gains and losses are reported as a separate component of stockholders' equity (deficit). The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the statement of operations and comprehensive loss. If any adjustment to fair value reflects a decline in the value of the investment, the Company considers available evidence to evaluate the extent to which the decline is "other than temporary" and reduces the investment to fair value through a charge to the statement of operations and comprehensive loss.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- § Level 1 — Quoted prices in active markets for identical assets or liabilities.
- § Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

- § Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above. The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds all cash, cash equivalents and marketable securities balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including preclinical and clinical testing. These programs could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and other components.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs (non-current) until such financings are consummated. After consummation of the equity financing, these costs are recorded in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the equity financing no longer be considered probable of being consummated, all deferred offering costs will be charged to operating expenses in the statement of operations. The Company did not record any deferred offering costs as of December 31, 2013 or 2014.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the asset. Computer equipment is depreciated over three years. Manufacturing equipment is depreciated over five years. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

2. Summary of Significant Accounting Policies (Continued)

asset over its fair value, determined based on discounted cash flows. To date, the Company has not recorded any impairment losses on long-lived assets.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is identifying, developing and commercializing innovative and differentiated topical drugs to address significant unmet needs in dermatology. No revenue has been generated since inception, and all tangible assets are held in the United States.

Recently Issued and Adopted Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2014-10, *Development Stage Entities*. The amendments in this update removed all incremental financial reporting requirements, including inception-to-date information and certain other disclosures currently required under GAAP, in the financial statements of development stage companies. The amendments are effective for annual reporting periods beginning after December 15, 2014 and interim reporting periods beginning after December 15, 2015. Early adoption is permitted. The Company elected to early adopt this guidance and, therefore, has not presented inception-to-date disclosures in its financial statements.

In August 2014, the FASB issued ASU 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early application is permitted. The Company is currently evaluating the potential impact of the adoption of this standard, but believes its adoption will have no impact on its financial position, results of operations or cash flows.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities as of December 31, 2013 and 2014 that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values:

	Fair Value Measurements as of December 31, 2013 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 9,465	\$ —	\$ —	\$ 9,465
Marketable securities	—	4,538	—	4,538
	<u>\$ 9,465</u>	<u>\$ 4,538</u>	<u>\$ —</u>	<u>\$ 14,003</u>

ACLARIS THERAPEUTICS, INC.
NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

3. Fair Value of Financial Assets and Liabilities (Continued)

	Fair Value Measurements as of December 31, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 10,012	\$ —	\$ —	\$ 10,012
Marketable securities	—	5,891	—	5,891
	<u>\$ 10,012</u>	<u>\$ 5,891</u>	<u>\$ —</u>	<u>\$ 15,903</u>

As of December 31, 2013 and 2014, the Company's cash equivalents, which were invested in money market funds, were valued based on Level 1 inputs. In determining the fair value of its marketable securities valued using Level 2 inputs, the Company primarily relied on quoted prices from a third-party pricing service for identical securities in markets that are not active. The models used by the third-party pricing service are based on market data and utilize available trade, bid and other observable market data for identical securities. Quarterly, the Company compares the prices obtained from the third-party pricing service to other available independent pricing information to validate the reasonableness of the valuations provided. The Company evaluates whether adjustments to third-party pricing is necessary and, historically, the Company has not made adjustments to prices obtained from the third-party pricing service. During the years ended December 31, 2013 and 2014, there were no transfers between Level 1, Level 2 and Level 3.

As of December 31, 2013 and 2014, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

	December 31, 2013			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	\$ 3,734	\$ 2	\$ —	\$ 3,736
U.S. government agency debt securities	801	1	—	802
	<u>\$ 4,535</u>	<u>\$ 3</u>	<u>\$ —</u>	<u>\$ 4,538</u>

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	\$ 5,096	\$ —	\$ (6)	\$ 5,090
U.S. government agency debt securities	801	—	—	801
	<u>\$ 5,897</u>	<u>\$ —</u>	<u>\$ (6)</u>	<u>\$ 5,891</u>

As of December 31, 2013 and 2014, the Company's corporate debt securities had credit ratings of A and above and remaining maturities of less than 10 months and less than 13 months, respectively.

ACLARIS THERAPEUTICS, INC.**NOTES TO FINANCIAL STATEMENTS (Continued)**

(Amounts in thousands, except share and per share data)

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2013	2014
Computer equipment	\$ 34	\$ 36
Construction in progress	—	506
	<u>34</u>	<u>542</u>
Less: Accumulated depreciation	(15)	(27)
	<u>\$ 19</u>	<u>\$ 515</u>

Depreciation expense was \$11 and \$12 for the years ended December 31, 2013 and 2014, respectively. Construction in progress as of December 31, 2014 consisted of manufacturing equipment, which is expected to be placed into service in 2015.

5. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2013	2014
Clinical trial expenses	\$ —	\$ 163
Other	14	25
	<u>\$ 14</u>	<u>\$ 188</u>

6. Redeemable Convertible Preferred Stock

The Company has issued Series A and Series B redeemable convertible preferred stock (collectively, the "Redeemable Preferred Stock"). The Redeemable Preferred Stock is classified outside of stockholders' equity (deficit) because the shares contain redemption features that are not solely within the control of the Company. As of December 31, 2013 and 2014, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 20,890,000 shares and 34,090,000 shares, respectively, of \$0.00001 par value preferred stock.

In September 2014, the Company entered into a stock purchase agreement pursuant to which the Company agreed to sell to the investors an initial issuance (the "First Tranche") of 6,451,057 shares of Series B redeemable convertible preferred stock at \$1.65 per share for gross proceeds of \$10,644. Per the terms of that stock purchase agreement, upon the successful attainment of two specified milestones, the Company may call a second tranche of 6,451,057 shares of Series B redeemable convertible preferred stock at \$1.65 per share (the "purchased put option"). The Company has the right, but not the obligation, to exercise its purchased put option after successful attainment of the specified milestones as confirmed by a vote of five-sixths of the members of the Company's board of directors and 60% of voting stockholders of the Company. The two milestones relate to (i) the successful achievement of the primary efficacy endpoint and demonstrated safety of a specified Phase 2b clinical trial of A-101 in patients with SK, and (ii) the occurrence of an end-of-Phase 2 meeting with the U.S. Food and Drug Administration ("FDA"), as a result

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

6. Redeemable Convertible Preferred Stock (Continued)

of which the FDA has not raised any objection to the Company proceeding to a Phase 3 clinical trial of A-101 in patients with SK. Upon the closing of a qualified initial public offering, the Company will amend its certificate of incorporation to eliminate all authorized shares of Series A and Series B redeemable preferred stock, which will eliminate the Company's purchased put option.

In connection with the initial issuance of Series B redeemable convertible preferred stock in September 2014, the Company recorded the First Tranche transaction, net of issuance costs of \$60, and the \$1,039 issuance-date fair value of the purchased put option. The purchased put option was recorded as a charge to accumulated deficit within stockholders' deficit and as an increase to the carrying value of Series B redeemable convertible preferred stock based on the Company's conclusion that the purchased put option met the equity classification criteria at time of issuance as the purchased put option (i) is a freestanding financial instrument that does not require the Company to issue shares that are potentially redeemable and (ii) requires gross physical settlement in all circumstances.

The fair value of the purchased put option was determined on the date of its issuance using the Black-Scholes option-pricing model with the following assumptions and inputs: risk-free interest rate of 0.08%, expected term of nine months, expected volatility of 80.0%, no expected dividends and fair value of underlying instruments of \$1.65. The fair value calculation also included an estimate of a 60% probability of occurrence of the successful attainment of the specified milestones that trigger the Company's ability to exercise the purchased put option, as well as an estimate of a 60% probability of the Company exercising the purchased put option, if it became exercisable.

Redeemable Preferred Stock consisted of the following at December 31, 2013 and 2014:

	December 31, 2013				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A redeemable convertible preferred stock	20,890,000	20,890,000	\$ 23,000	\$ 23,169	20,890,000
	<u>20,890,000</u>	<u>20,890,000</u>	<u>\$ 23,000</u>	<u>\$ 23,169</u>	<u>20,890,000</u>
	December 31, 2014				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A redeemable convertible preferred stock	20,890,000	20,890,000	\$ 24,879	\$ 25,023	20,890,000
Series B redeemable convertible preferred stock	13,200,000	6,451,057	11,798	10,859	6,451,057
	<u>34,090,000</u>	<u>27,341,057</u>	<u>\$ 36,677</u>	<u>\$ 35,882</u>	<u>27,341,057</u>

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

6. Redeemable Convertible Preferred Stock (Continued)

The holders of the Redeemable Preferred Stock have the following rights and preferences:

Dividends

The holders of Redeemable Preferred Stock are entitled to receive, on a *pari passu* basis, cumulative dividends, in cash, at the rate of 8% per year on the applicable Original Issue Price (as defined below) and accrued but unpaid dividends. Dividends accrue on a daily basis, whether or not earned or declared, irrespective of the availability of profits or surplus and compound annually on the anniversary of the date of original issuance. Dividends on the Redeemable Preferred Stock are payable upon redemption of the Redeemable Preferred Stock or upon liquidation. The Original Issue Price for Series A and Series B redeemable convertible preferred stock is \$1.00 and \$1.65, respectively, per share, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or recapitalization affecting the Redeemable Preferred Stock.

Liquidation Preference

In the event of any liquidation dissolution or winding up of the Company, either voluntary or involuntary, or in the event of Deemed Liquidation Event (as defined below), holders of Redeemable Preferred Stock are entitled to receive, in preference to all other stockholders, and to the extent available, an amount equal to the Original Issue Price, adjusted for any stock dividends, stock splits or recapitalizations, plus any accruing dividend accrued but unpaid, whether or not earned or declared. In the event that proceeds are not sufficient to permit payment in full to these holders, the proceeds will be ratably distributed among the holders of Redeemable Preferred Stock on a *pari passu* basis to the full preferential amount each such holder is otherwise entitled to receive.

After payments have been made in full to the holders of Redeemable Preferred Stock, then, to the extent available, holders of the common stock and Redeemable Preferred Stock are entitled to participate in the distribution of the remaining assets, pro rata based on the number of shares of common stock held by each (on an as-converted to common basis).

Unless the holders of at least 60% of the then outstanding shares of the Redeemable Preferred Stock, voting together as a single class on an as-converted basis, elect otherwise, a Deemed Liquidation Event shall include a merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

Conversion

Each share of Redeemable Preferred Stock is convertible into common stock at the option of the stockholder at any time after the date of issuance. Each share of the Redeemable Preferred Stock will be converted into shares of common stock, at the applicable conversion ratio of each series of Redeemable Preferred Stock then in effect, upon the earlier of (i) a qualified public offering with net proceeds of not less than \$50,000 and a price of not less than \$4.95 per share, subject to appropriate adjustment for any stock dividend, stock split, combination or other similar recapitalization, and (ii) the date specified by written consent or agreement of the holders of 60% of the then-outstanding shares of Series A redeemable convertible preferred stock and the holders of 60% of the then-outstanding shares of Series B redeemable convertible preferred stock.

The conversion ratio of each series of Redeemable Preferred Stock is determined by dividing the Original Issue Price of each series of preferred stock by the Conversion Price of each series. The Conversion Price of

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

6. Redeemable Convertible Preferred Stock (Continued)

each series is \$1.00 for Series A and \$1.65 for Series B and is subject to adjustment as set forth in the Company's certificate of incorporation, as amended and restated. As of December 31, 2014, all outstanding shares of Series A and Series B redeemable convertible preferred stock were convertible into common stock on a one-for-one basis.

Redemption

At the written election of the holders of at least 60% of the outstanding Series A redeemable convertible preferred stock, voting together as a single class, the shares of Series A redeemable convertible preferred stock outstanding shall be redeemed at any time on or after September 30, 2019, in three annual installments commencing sixty days after receipt of the required vote, at the Original Issue Price per share of Series A redeemable convertible preferred stock plus all accruing dividends accrued thereon, whether or not declared, together with any other dividends declared but unpaid thereon.

At the written election of the holders of at least 60% of the outstanding Series B redeemable convertible preferred stock, voting together as a single class, the shares of Series B redeemable convertible preferred stock outstanding shall be redeemed at any time on or after September 30, 2019, in three annual installments commencing sixty days after receipt of the required vote, at the Original Issue Price per share of Series B redeemable convertible preferred stock plus all accruing dividends accrued thereon, whether or not declared, together with any other dividends declared but unpaid thereon.

The Company shall redeem the shares on a pro rata basis in accordance with the number of shares of Series A or Series B redeemable convertible preferred stock held by each stockholder. No shares of Series A redeemable convertible preferred stock shall be redeemed so long as any shares of Series B redeemable convertible preferred stock remain issued and outstanding.

The carrying values of the Series A and Series B redeemable convertible preferred stock are being accreted to their redemption values through September 30, 2019.

Voting Rights

The holders of Redeemable Preferred Stock are entitled to vote, together with the holders of common stock, on all matters submitted to stockholders for a vote. Holders of Redeemable Preferred Stock have the right to vote the number of shares equal to the number of shares of common stock into which such Redeemable Preferred Stock could convert on the record date for determination of stockholders entitled to vote. The holders of the majority of Redeemable Preferred Stock, voting separately as a class, are entitled to elect three directors of the Company.

7. Stockholders' Equity (Deficit)

Common Stock

As of December 31, 2013 and 2014, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 41,000,000 shares and 77,000,000 shares, respectively, of \$0.00001 par value common stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of the Redeemable Preferred Stock. When dividends are declared on shares of common stock, the Company must declare at the same time a dividend payable to the holders of Redeemable Preferred Stock equivalent to the dividend amount they

ACLARIS THERAPEUTICS, INC.**NOTES TO FINANCIAL STATEMENTS (Continued)****(Amounts in thousands, except share and per share data)****7. Stockholders' Equity (Deficit) (Continued)**

would receive if each preferred share were converted into common stock. The Company may not pay dividends to common stockholders until all dividends accrued or declared but unpaid on the Redeemable Preferred Stock have been paid in full. No dividends had been declared through December 31, 2014.

As of December 31, 2013 and 2014, the Company had reserved 21,470,000 shares and 29,067,018 shares, respectively, for the conversion of the outstanding shares of Series A and Series B redeemable convertible stock (see Note 6) and the exercise of outstanding stock options and the number of shares remaining available for future grant under the Company's 2012 Plan (see Note 8).

Restricted Common Stock

The Company has granted restricted common stock with time-based vesting conditions. Unvested shares of restricted common stock may not be sold or transferred by the holder. These restrictions lapse according to the time-based vesting conditions of each award.

In July 2012, the Company issued 9,420,000 shares of common stock to its founders in connection with the Company's formation, of which 6,620,000 shares were subject to vesting pursuant to restricted stock agreements, with 25% of such shares vesting in July 2013 and the remaining 75% vesting in equal monthly installments over a three-year period thereafter. The estimated grant-date fair value of these restricted common shares was \$0.00001 per share, equal to the par value of each share. As of December 31, 2013 and 2014, 4,275,417 and 2,620,417 shares, respectively, were subject to repurchase.

The table below summarizes the Company's restricted stock activity since January 1, 2013:

	<u>Number of Shares</u>	<u>Weighted Average Grant Date Fair Value Per Share</u>
Unvested restricted common stock as of December 31, 2012	6,620,000	\$ 0.00001
Vested	(2,344,583)	\$ 0.00001
Unvested restricted common stock as of December 31, 2013	4,275,417	\$ 0.00001
Vested	(1,655,000)	\$ 0.00001
Unvested restricted common stock as of December 31, 2014	<u>2,620,417</u>	\$ 0.00001

The aggregate intrinsic value of restricted stock awards that vested during the years ended December 31, 2013 and 2014 was \$281 and \$488, respectively.

8. Stock-Based Awards**2012 Equity Compensation Plan**

The Company's 2012 Equity Compensation Plan, as amended and restated, (the "2012 Plan") provides for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the board of directors and consultants of the Company. The 2012 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or their committee if so delegated,

ACLARIS THERAPEUTICS, INC.**NOTES TO FINANCIAL STATEMENTS (Continued)**

(Amounts in thousands, except share and per share data)

8. Stock-Based Awards (Continued)

except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock options may not be greater than ten years. The Company generally grants stock-based awards with service conditions only ("service-based" awards).

Stock options granted under the 2012 Plan generally vest over four years and expire after ten years.

The total number of shares of common stock that may be issued under the 2012 Plan was 580,000 shares as of December 31, 2013, all of which shares remained available for future grant at December 31, 2013. On September 30, 2014, the Company effected an increase in the number of shares of common stock reserved for issuance under the 2012 Plan to 1,725,961 shares. The number of shares reserved for issuance under the 2012 Plan will be automatically increased to 1,980,708 shares upon the Company's exercise of the purchased put option (see Note 6). As of December 31, 2014, no shares remained available for grant under the 2012 Plan.

As required by the 2012 Plan, the exercise price for stock options granted is not to be less than the fair value of common shares as determined by the Company as of the date of grant. The Company values its common stock by taking into consideration its most recently available valuation of common shares performed by management and the board of directors as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

Stock Option Valuation

The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors were as follows, presented on a weighted average basis:

	<u>Year Ended</u> <u>December 31, 2014</u>
Risk-free interest rate	1.87%
Expected term (in years)	6.4
Expected volatility	113.9%
Expected dividend yield	0%

The Company recognizes compensation expense for only the portion of awards that are expected to vest. For the year ended December 31, 2014, the Company applied an expected forfeiture rate of 0%.

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

8. Stock-Based Awards (Continued)

Stock Options

There were no stock options granted, exercised, forfeited or canceled during year ended December 31, 2013. The following table summarizes stock option activity under the 2012 Plan from January 1, 2014 through December 31, 2014:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2013	—	\$ —	—	\$ —
Granted	1,725,961	0.35		
Exercised	—	—		
Forfeited and canceled	—	—		
Outstanding as of December 31, 2014	<u>1,725,961</u>	\$ 0.35	9.77	\$ 305
Options vested and expected to vest as of December 31, 2014	<u>1,725,961</u>	\$ 0.35	9.77	\$ 305
Options exercisable as of December 31, 2014	<u>(1)</u>	\$ —	—	\$ —

(1) All options granted to date under the 2012 Plan are exercisable immediately, subject to a repurchase right in the Company's favor that lapses as the option vests. This amount reflects the number of shares under options that were vested, as opposed to exercisable, as of December 31, 2014.

The weighted average grant-date fair value of stock options granted during the year ended December 31, 2014 was \$0.40 per share.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock.

Stock-Based Compensation

The Company recorded no stock-based compensation expense for the year ended December 31, 2013. The Company recorded stock-based compensation expense related to stock options for the year ended December 31, 2014 in the following expense categories of its statements of operations and comprehensive loss:

	Year Ended December 31, 2014
Research and development	\$ 10
General and administrative	17
	<u>\$ 27</u>

As of December 31, 2014, the Company had an aggregate of \$670 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 3.78 years.

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

9. Net Loss per Share and Unaudited Pro Forma Net Loss per Share

Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2014</u>
Numerator:		
Net loss	\$ (5,236)	\$ (8,517)
Accretion of redeemable convertible preferred stock to redemption value	(1,740)	(2,054)
Net loss attributable to common stockholders	<u>\$ (6,976)</u>	<u>\$ (10,571)</u>
Denominator:		
Weighted average shares of common stock outstanding	9,420,000	9,420,000
Less: Weighted average shares of unvested restricted common stock outstanding	<u>(5,689,346)</u>	<u>(3,485,698)</u>
Weighted average common shares outstanding used in calculating net loss per share attributable to common stockholders, basic and diluted	<u>3,730,654</u>	<u>5,934,302</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.87)</u>	<u>\$ (1.78)</u>

The Company's potential dilutive securities, which include stock options, unvested restricted common stock and redeemable convertible preferred stock, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The following potential common shares, presented based on amounts outstanding at each period end, were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2014</u>
Stock options to purchase common stock	—	1,725,961
Unvested restricted common stock	4,275,417	2,620,417
Redeemable convertible preferred stock (as converted to common stock)	<u>20,890,000</u>	<u>27,341,057</u>
	<u>25,165,417</u>	<u>31,687,435</u>

Unaudited Pro Forma Net Loss per Share

The unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2014 gives effect to adjustments arising upon the closing of a qualified initial public offering. The unaudited pro forma net loss attributable to common stockholders used in the calculation of unaudited basic and diluted pro forma net loss per share attributable to common stockholders does not include the effects of the accretion of redeemable convertible preferred stock to redemption value because the calculation assumes that the conversion of redeemable convertible preferred stock into common stock had occurred on the later of January 1, 2014 or the issuance date of the redeemable convertible preferred stock.

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

9. Net Loss per Share and Unaudited Pro Forma Net Loss per Share (Continued)

The unaudited pro forma basic and diluted weighted average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2014 give effect to the conversion upon a qualified initial public offering of all outstanding shares of Redeemable Preferred Stock as of December 31, 2014 into 27,341,057 shares of common stock as if the conversion had occurred on the later of January 1, 2014 or the issuance date of the Redeemable Preferred Stock.

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	<u>Year Ended</u> <u>December 31, 2014</u> <u>(unaudited)</u>
Numerator:	
Net loss attributable to common stockholders	\$ (10,571)
Accretion of redeemable convertible preferred stock to redemption value	2,054
Pro forma net loss attributable to common stockholders	<u>\$ (8,517)</u>
Denominator:	
Weighted average common shares outstanding, basic and diluted	5,934,302
Pro forma adjustment for assumed conversion of all outstanding shares of redeemable convertible preferred stock upon the closing of the proposed initial public offering	22,533,693
Pro forma weighted average common shares outstanding, basic and diluted	<u>28,467,995</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.30)</u>

10. Commitments and Contingencies***Assignment Agreement and Finder's Services Agreement***

In August 2012, the Company entered into an assignment agreement with the Miller Estate under which it acquired intellectual property. The initial consideration paid by the Company during the year ended December 31, 2012 was \$405. In November 2013, upon the achievement of a clinical milestone, the Company made a milestone payment of \$200. These two payments were recorded as research and development expense during the years ended December 31, 2012 and 2013, respectively. In addition, the Company is obligated to pay royalties on sales of A-101 or related products at rates ranging in low single-digit percentages of net sales, as defined in the agreement. No royalty payments were made during the years ended December 31, 2013 or 2014 pursuant to the agreement.

In August 2012, the Company entered into a finder's services agreement with KPT Consulting, LLC ("KPT") to provide certain business development consulting services to the Company in connection with the intellectual property acquired by the Company under the assignment agreement. The initial consideration paid by the Company during the year ended December 31, 2012 was \$200. In November 2013, upon the achievement of a milestone specified in the agreement, the Company paid an additional \$200. These two payments were recorded as general and administrative expense during the years ended December 31, 2012 and 2013, respectively.

ACLARIS THERAPEUTICS, INC.**NOTES TO FINANCIAL STATEMENTS (Continued)**

(Amounts in thousands, except share and per share data)

10. Commitments and Contingencies (Continued)

Under the finder's services agreement, the Company is obligated to make additional future milestone payments to KPT of up to \$1,300 upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals, as well as milestone payments of up to \$4,500 upon the achievement of specified commercial milestones. In addition, the Company is obligated to pay royalties on sales of A-101 or related products at a low single-digit percentage of net sales, as defined in the agreement. No royalty payments were made during the years ended December 31, 2013 or 2014 pursuant to the agreement.

Both agreements will terminate upon the expiration of the last pending, viable patent claim of the patents acquired under the assignment agreement, but no sooner than 15 years from the effective date of the agreements.

Lease

In September 2012, the Company entered into a sublease agreement for its office space with related parties (see Note 12), which, as amended, has a term ending on November 30, 2016. Rent expense under operating leases was \$71 and \$66 for the years ended December 31, 2013 and 2014, respectively. The Company recognizes rent expense on a straight-line basis over the lease period and has accrued for rent expense incurred but not yet paid. As part of the most recent amendment to the sublease agreement on December 2, 2014, the Company increased the amount of office space to be leased and, accordingly, agreed to new monthly lease terms commencing in January 2015.

Future minimum lease payments under the sublease are as follows:

Years Ending December 31,	
2015	\$ 104
2016	97
Total	<u>\$ 201</u>

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its financial statements as of December 31, 2013 or 2014.

Supply Agreement

In January 2015, the Company executed a clinical and commercial supply agreement with a third party for the manufacture and assembly of certain components for the product applicator that the Company intends to use to dispense A-101 in Phase 3 clinical trials and for the commercial drug product. The agreement has

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

10. Commitments and Contingencies (Continued)

a term of three years and automatically renews for consecutive one-year terms. If the agreement is terminated by the Company without cause or by the third party for cause prior to the FDA's approval of A-101, the Company will owe a termination fee equal to \$375. If the agreement is terminated by the Company without cause or by the third party for cause after the FDA approval of A-101, the Company will owe a termination fee equal to \$275. The Company's obligation to pay the termination fee expires after the third anniversary date of the FDA's approval of A-101.

11. Income Taxes

During the years ended December 31, 2013 and 2014, the Company recorded no income tax benefits for the net operating losses incurred in each year, due to its uncertainty of realizing a benefit from those items.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2013	2014
Federal statutory income tax rate	(34.0)%	(34.0)%
Research and development tax credits	(1.6)	(1.0)
State taxes, net of federal benefit	(6.6)	(6.6)
Change in deferred tax asset valuation allowance	42.2	41.6
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>

Net deferred tax assets as of December 31, 2013 and 2014 consisted of the following:

	December 31,	
	2013	2014
Deferred tax assets:		
Net operating loss carryforwards	\$ 2,289	\$ 5,606
Research and development tax credit carryforwards	113	203
Capitalized research and development expenses	501	620
Stock-based compensation expenses	—	11
Other	—	4
Total deferred tax assets	<u>2,903</u>	<u>6,444</u>
Deferred tax liabilities:		
Other	(4)	—
Total deferred tax liabilities	<u>(4)</u>	<u>—</u>
Valuation allowance	(2,899)	(6,444)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2014, the Company had federal and state net operating loss carryforwards of \$13,810 and \$13,810, respectively, both of which begin to expire in 2032. As of December 31, 2014, the Company

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

11. Income Taxes (Continued)

also had federal research and development tax credit carryforwards of \$203, which begin to expire in 2032, and the Company had no state research and development tax credit carryforwards. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2013 and 2014. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2013 and 2014 related primarily to the increases in net operating loss carryforwards and research and development tax credit carryforwards and were as follows:

	<u>Year Ended December 31,</u>	
	<u>2013</u>	<u>2014</u>
Valuation allowance at beginning of year	\$ (690)	\$ (2,899)
Decreases recorded as benefit to income tax provision	—	—
Increases recorded to income tax provision	(2,209)	(3,545)
Valuation allowance as of end of year	<u>\$ (2,899)</u>	<u>\$ (6,444)</u>

The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2013 or 2014. The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from 2012 to the present. All open years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

ACLARIS THERAPEUTICS, INC.

NOTES TO FINANCIAL STATEMENTS (Continued)

(Amounts in thousands, except share and per share data)

12. Related Party Transactions

In September 2012, the Company entered into a sublease agreement for its leased office space in Malvern, Pennsylvania with Ceptaris Therapeutics ("Ceptaris"), a company that was acquired in September 2013. Upon the acquisition, the Company terminated the sublease agreement with Ceptaris and entered into a direct sublease agreement with NeXeption, Inc. ("NeXeption") for the leased space. A member of the Company's board of directors was an executive officer of Ceptaris and is a current executive officer of NeXeption. Total payments made during the years ended December 31, 2013 and 2014 under these sublease agreements were \$68 and \$66, respectively (see Note 10).

In November 2012, the Company entered into a services agreement with Ceptaris, under which Ceptaris provided certain professional services, administrative support and office services to the Company. In September 2013, Ceptaris terminated the agreement in accordance with its terms. In September 2013, the Company entered into a second services agreement with Ceptaris, under which Ceptaris provided certain pharmaceutical development and management services to the Company. In December 2013, Ceptaris terminated the agreement in accordance with its terms, effective February 4, 2014. Total payments made to Ceptaris in connection with these agreements during the years ended December 31, 2013 and 2014 were \$166 and \$10, respectively. As of December 31, 2013, there was \$8 included in accounts payable to Ceptaris.

In February 2014, the Company entered into a services agreement with NST, LLC ("NST"), under which NST provides certain pharmaceutical development, management and other administrative services to the Company. Certain officers of the Company are also founding partners of NST. Under the same agreement, the Company also provides services to NST and is reimbursed for those services. The Company may offset any payments owed by the Company to NST against payments that are owed by NST to the Company for the provision of NST personnel, including consultants, to the Company. During the year ended December 31, 2014, gross expenses incurred by the Company under the services agreement totaled \$467 and gross expenses charged to NST by the Company totaled \$413. For the year ended December 31, 2014, the Company recorded \$309 of general and administrative expenses and \$255 as a reduction of research and development expenses related to these transactions. During the year ended December 31, 2014, payments made to NST by the Company totaled \$131 and receipts received from NST by the Company totaled \$77. No amounts were due to or due from NST at December 31, 2014 related to this agreement.

13. 401(k) Savings Plan

The Company has a defined contribution savings plan under Section 401(k) of the Internal Revenue Code. This plan covers substantially all employees who meet minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Company contributions to the plan may be made at the discretion of the Company's board of directors. The Company has elected to match employee contributions to the 401(k) Plan of up to 100% of the employee's first 3% of earnings plus up to 50% of the next 2% of earnings, subject to certain limitations. Company contributions under the 401(k) Plan were \$51 and \$60 for the year ended December 31, 2013 and 2014, respectively.

14. Subsequent Events

For its financial statements as of December 31, 2014 and for the year then ended, the Company evaluated subsequent events through April 2, 2015, the date on which those financial statements were issued.

Shares



Aclaris Therapeutics, Inc.

Common Stock

Preliminary Prospectus

Jefferies

Citigroup

William Blair

, 2015

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and The NASDAQ Global Market initial listing fee.

	Amount to be Paid
SEC registration fee	\$ *
FINRA filing fee	*
NASDAQ Global Market initial listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous fees and expenses	*
Total	\$ *

* To be filed by amendment.

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 102 of the Delaware General Corporation Law permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit.

Section 145 of the Delaware General Corporation Law provides that a corporation has the power to indemnify a director, officer, employee or agent of the corporation and certain other persons serving at the request of the corporation in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlements actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he is or is threatened to be made a party by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification will be made with respect to any claim, issue or matter as to which such person will have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court may deem proper.

As permitted by the Delaware General Corporation Law, our amended and restated certificate of incorporation and bylaws to be in effect upon the closing of this offering will provide that: (i) we are

required to indemnify our directors to the fullest extent permitted by the Delaware General Corporation Law; (ii) we may, in our discretion, indemnify our officers, employees and agents as set forth in the Delaware General Corporation Law; (iii) we are required, upon satisfaction of certain conditions, to advance all expenses incurred by our directors in connection with certain legal proceedings; (iv) the rights conferred in the bylaws are not exclusive; and (v) we are authorized to enter into indemnification agreements with our directors, officers, employees and agents.

We have entered into indemnification agreements with each of our directors, and we expect to enter into indemnification agreements with each of our executive officers. These indemnification agreements require us to indemnify the officer or director against expenses, judgments, fines, settlements and other amounts that any such person becomes legally obligated to pay (including with respect to a derivative action) in connection with any proceeding, whether actual or threatened, to which such person may be made a party by reason of the fact that such person is or was a director or officer of us or any of our affiliates, provided such person acted in good faith and in a manner such person reasonably believed to be in, or not opposed to, our best interests. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder. We intend to enter into similar indemnification agreements with our executive officers in connection with this offering. At present, no litigation or proceeding is pending that involves any of our directors or officers regarding which indemnification is sought, nor are we aware of any threatened litigation that may result in claims for indemnification.

We maintain a directors' and officers' liability insurance policy. The policy insures directors and officers against unindemnified losses arising from certain wrongful acts in their capacities as directors and officers and reimburses us for those losses for which we have lawfully indemnified the directors and officers. The policy contains various exclusions.

In addition, the underwriting agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification by the underwriters of us and our officers and directors for certain liabilities arising under the Securities Act, or otherwise. Our investors' rights agreement with certain investors also provides for cross-indemnification in connection with the registration of our common stock on behalf of such investors.

Item 15. Recent Sales of Unregistered Securities.

Issuances of Capital Stock

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2012 through the date of the prospectus that forms a part of this registration statement.

- 1) In July 2012, we issued an aggregate of 9,420,000 shares of our common stock to 14 investors at a purchase price of \$0.00001 per share, for aggregate consideration of \$94.
- 2) In August 2012, we issued an aggregate of 20,890,000 shares of our Series A redeemable convertible preferred stock to 31 investors at a purchase price of \$1.00 per share, for aggregate consideration of \$20.9 million.
- 3) In September 2014, we issued an aggregate of 6,451,057 shares of our Series B redeemable convertible preferred stock to 25 investors at a purchase price of \$1.65 per share, for aggregate consideration of \$10.6 million.

The offers, sales and issuances of the securities described in the paragraphs above were exempt from registration under Section 4(a)(2) of the Securities Act and Regulation D promulgated under the Securities Act. Each of the purchasers represented to us that they acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. The purchasers also represented to us that they were accredited investors as defined in Rule 501 promulgated under the Securities Act.

Stock Option Grants

From January 1, 2012 through the date of the prospectus that is a part of this registration statement, we have granted options under our 2012 equity compensation plan to purchase an aggregate of 1,725,961 shares of our common stock to employees, consultants and directors, having exercise prices ranging from \$0.12 to \$0.44 per share. We have not issued any shares of our common stock upon the exercise of stock options.

The offers, sales and issuances of the securities described in the foregoing paragraph were exempt from registration under Rule 701 promulgated under the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or consultants and received the securities under our 2012 equity compensation plan. Appropriate legends were affixed to the securities issued in these transactions.

Item 16. Exhibits and Financial Statement Schedules.

The exhibits to the registration statement are listed in the Exhibit Index attached hereto and are incorporated by reference herein.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this Registration Statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Malvern, Commonwealth of Pennsylvania, on the day of , 2015.

ACLARIS THERAPEUTICS, INC.

By: _____
Neal Walker
President and Chief Executive Officer

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Neal Walker, Kamil Ali-Jackson, Frank Ruffo and Brent B. Siler, and each of them, his true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to (i) act on, sign and file with the Securities and Exchange Commission any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto and any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
_____ Neal Walker	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	, 2015
_____ Frank Ruffo	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	, 2015
_____ Stephen A. Tullman	Chairman of the Board of Directors	, 2015
_____ Albert Cha, M.D., Ph.D.	Director	, 2015

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<hr/> Ketan Patel, M.D.	Director	, 2015
<hr/> Christopher Molineaux	Director	, 2015
<hr/> Anand Mehra, M.D.	Director	, 2015

EXHIBIT INDEX

Exhibit Number	Description of Document
1.1†	Form of Underwriting Agreement.
3.1*	Second Amended and Restated Certificate of Incorporation, as currently in effect.
3.2†	Form of Certificate of Amendment of Certificate of Incorporation to be filed prior to the closing of this offering.
3.3†	Form of Amended and Restated Certificate of Incorporation to be effective upon the closing of this offering.
3.4*	Bylaws, as currently in effect.
3.5†	Form of Amended and Restated Bylaws to be effective upon closing of this offering.
4.1†	Specimen stock certificate evidencing shares of Common Stock.
5.1†	Opinion of Cooley LLP as to legality.
10.1†#	Clinical and Commercial Supply Agreement, by and between the Registrant and PeroxyChem LLC, dated as of August 6, 2014.
10.2†#	Services Agreement, by and between the Registrant and NST, LLC, dated as of February 5, 2014, as amended on December 19, 2014.
10.3†#	Assignment Agreement, by and between the Registrant and Mickey J. Miller, II, as personal representative of the estate of Mickey J. Miller, dated as of August 20, 2012.
10.4†#	Finder's Services Agreement, by and between the Registrant and KPT Consulting, LLC, dated as of August 25, 2012.
10.5*	Amended and Restated Investors' Rights Agreement, dated as of September 30, 2014, by and among the Registrant and certain of its stockholders.
10.6*	Amended and Restated Sublease, by and between the Registrant and NeXeption, Inc., dated as of March 3, 2014, as amended on December 2, 2014.
10.7*+	Amended and Restated 2012 Equity Compensation Plan, as currently in effect.
10.8*+	Form of Stock Option Grant under Amended and Restated 2012 Equity Compensation Plan.
10.9+†	Form of 2015 Equity Incentive Plan.
10.10+†	Form of Stock Option Grant Notice and Stock Option Agreement under 2015 Equity Incentive Plan.
10.11+†	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under 2015 Equity Incentive Plan.
10.12*	Form of Indemnification Agreement.
10.13+†	Form of Employment Agreement with Named Executive Officers to be effective upon the closing of this offering.
23.1†	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.

Exhibit Number	Description of Document
23.2†	Consent of Cooley LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).

† To be filed by amendment.

* Previously submitted.

+ Indicates management contract or compensatory plan.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and have been separately filed with the Securities and Exchange Commission.

